A Feasibility Study of an eHealth Intervention for Dietary Sodium Reduction in Primary Care

by

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The above committee determined that the thesis is acceptable in form and content and that a satisfactory knowledge of the field covered by the thesis was demonstrated by the candidate during an oral examination. A signed copy of the Certificate of Approval is available from the School of Graduate and Postdoctoral Studies.

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OVERALL THESIS ABSTRACT

This thesis assessed the feasibility of a randomized controlled trial (RCT) protocol to implement a Sodium Calculator (SC) into primary care settings to determine if it improves quality of sodium reduction advice provided by physicians, with the results informing a fully powered RCT. Upon protocol implementation, the originally developed protocol was not initially feasible, but is expected to be with modifications, including: 1) employing a recruitment agency to recruit physicians and patients; 2) schedule recruited patients in consecutive blood pressure follow-up appointments to minimize study burden and increase recruitment and protocol adherence; 3) implement detailed procedures to minimize reporting bias. As part of this work, two questionnaires were developed and validated to evaluate quality of dietary sodium advice provided by physicians, and their self-efficacy in doing so. This research is the first phase of intervention implementation research related to the quality of care patients receive in hypertension prevention and management.

Keywords: Hypertension; Primary Care; Dietary Counselling; Nutrition; Diet; Sodium; Physicians; Feasibility; Quality of Care; Self-efficacy

AUTHOR'S DECLARATION

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Katherine Jefferson

STATEMENT OF CONTRIBUTIONS

I hereby certify that I am the sole author of this thesis and that no part of this thesis has been published or submitted for publication. I have used standard referencing practices to acknowledge ideas, research techniques, or other materials that belong to others. Furthermore, I hereby certify that I am the sole source of the creative works and/or inventive knowledge described in this thesis. Specific contributions of individuals to the research presented within this thesis have been provided in more detail at the beginning of each chapter.

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LIST OF ABBREVIATIONS AND SYMBOLS

BMI	Body mass index
BP	Blood pressure
CDRR	Chronic Disease Risk Reduction
CDSS	Clinical decision support system
cm	Centimetre
CVD	Cardiovascular disease
DASH	Dietary Approaches to Stop Hypertension
DBP	Diastolic blood pressure
eHealth	Electronic health
EMR	Electronic medical record
g	Gram
kg	Kilogram
mg	Milligram
mHealth	Mobile health
mmHg	Millimetre of mercury
NHAMCS	National Hospital Ambulatory Medical Care Survey
NHIS	National Health Interview Survey
PSSC	Perceived Self-efficacy of Sodium Counselling
RCT	Randomized controlled trial
SAQ	Sodium Advice Quality
SBP	Systolic blood pressure
SC	Sodium Calculator
SMS	Short message service
WHO	World Health Organization

GLOSSARY OF TERMS

Brief intervention:

An intervention implemented in a short amount of time; generally 5 minutes of brief advice to 15-30 minutes of brief counselling, but has also been noted to be anywhere from 30 seconds to 60 minutes in risky health behaviours (i.e. substance use) (Miller & Rollnick, 2002).

Construct validity:

The extent to which an instrument measures the specific domain of content. It can be determined via expert opinion (Ginty, 2013). It has been noted to be of utmost importance, and should be prioritised during instrument development as it is a prerequisite for other types of validity (Zamanzadeh et al., 2015).

eHealth:

'...an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies (Eysenbach, 2001), or in simpler terms 'eHealth is the use of information and communication technology in healthcare' (Granja, Janssen, & Johansen, 2018).

Face and content validity:

The extent that a survey is subjectively viewed as covering the concept it aims to measure (Holden, 2010). It also examines if a survey appears to be a reasonable way to gather the information required, if it is well designed and seems like it would work reliably (Fink, 1995). It is related to the appearance and attractiveness of an instrument which may affect the acceptability by users (Nunnally, 1994).

Pilot study:

An investigation designed to test the feasibility of methods and procedures for a future large scale study, or to search for possible effects and associations that may be worth following up in a subsequent larger study (Leon, Davis, & Kraemer, 2011). It validates the feasibility of the study by assessing the inclusion and exclusion criteria of the participants, preparation of the intervention, storage and testing of the instruments used for measurements in the study, as well as training of researchers and research assistants etc. (Inglis et al., 2017).

Quality of care:

The extent to which healthcare provider care is consistent with up to date evidenced-based practice guidelines that leads to improvement in desired health outcomes (Hanefeld, Powell-Jackson, & Balabanova, 2017; Hrisos et al., 2009)

Shared decision making:

An approach where clinicians and patients share best available evidence to make decisions about care, and where patients are supported in making informed preferences (Elwyn et al., 2012).

Self-efficacy:

Self-efficacy is an individual's personal belief in their ability to perform a certain task (Bandura, 2006).

CHAPTER 1.0: INTRODUCTION

1.1 Background

Excess dietary sodium is a causal factor in developing hypertension (high blood pressure), increasing the risk for cardiovascular diseases, stroke and renal disease (Aburto et al., 2013; He, Li, & Macgregor, 2013; Mozaffarian et al., 2014; Nerenberg et al., 2018; O'Donnell et al., 2010; World Health Organization, 2012; Yoon et al., 2018). In Canada, hypertension affects 22.6% of adults, resulting in an economic burden of $13.9 billion annually (Padwal, Bienek, McAlister, Campbell, & Outcomes Research Task Force of the Canadian Hypertension Education, 2016; Weaver et al., 2015).

Hypertension is most often managed by primary care practitioners, making primary care settings a key location for integrating behavioural counselling, including dietary advice (Clarke & Hauser, 2016; Dysinger, 2013; Melvin et al., 2017; Wolfenden et al., 2016). Physician counselling strongly influences patient engagement in health behaviour change, making them critical agents of change (Arcand et al., 2013; Kreuter, Chheda, & Bull, 2000; Pool et al., 2014). However, dietary counselling is not consistently implemented. Although over half of physicians in a Canadian survey thought their patients would benefit from dietary counselling, actual implementation remains suboptimal with <20% of patients receiving dietary advice from their physician, lasting only 55 seconds on average (Wynn, Trudeau, Taunton, Gowans, & Scott, 2010).

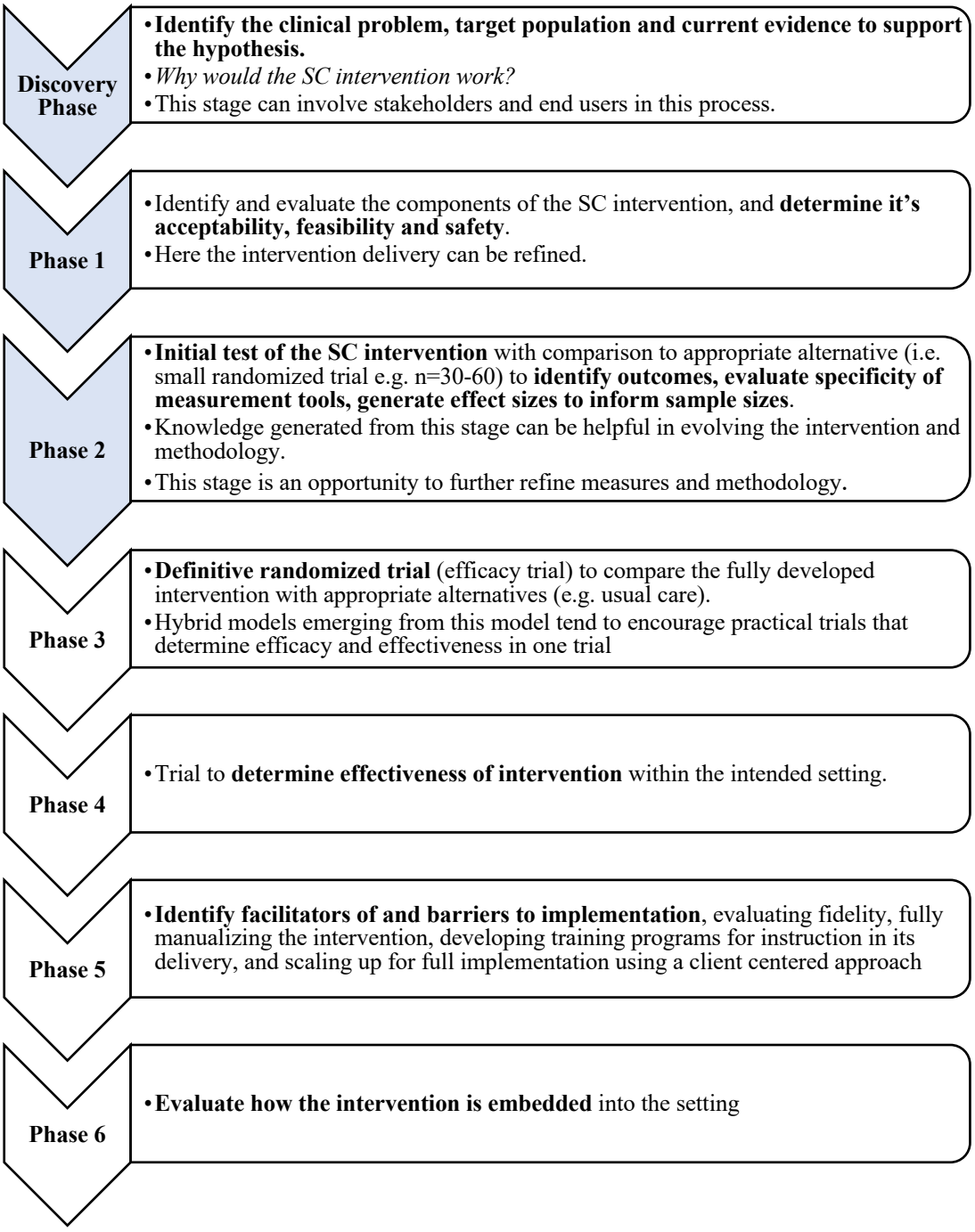
Electronic health (eHealth) tools are a promising strategy to minimize barriers for physicians in providing dietary counselling and advice to patients by allowing them to provide more effective and efficient care, and encourage shared decision making and patient self-management (Party, 2016; Stoffers, 2018). Health interventions utilizing

eHealth tools are therefore recommended by the WHO as a means to enhance patient access to care, increase shared decision making, and improve healthcare provider quality of care (Noar & Haarington, 2010; Schulz, 2014; Neuhauser & Kreps, 2010; Solomon, 2008; WHO, 2013). In Ontario, this is a particularly important time for innovative eHealth interventions, as they have the potential to provide a means for improving care integration and efficiency of the Ontario health system as it undergoes transformation. For example, aims of the newly proposed agency *Ontario Health* are to provide care that is more easily accessible to patients; provide more clinical guidance and effective support for healthcare providers in order to facilitate better quality patient care; efficient healthcare spending; and the advancement of digital-first approaches to healthcare (Government of Ontario, 2019; Ministry of Health and Long Term Care, 2019). Currently there are no feasible, evidenced eHealth interventions that have been integrated in primary care settings to support the provision of dietary sodium reduction advice. However, the eHealth tool, the Sodium Calculator (SC), developed to rapidly screen and assess sodium intake and provide users with personalized feedback, may serve this purpose.

It is hypothesized that the SC can be implemented as a brief screening and clinical decision support tool at point of service to assist physicians in providing higher quality nutrition care to their patients. Therefore, the overall aim of this thesis was to determine the feasibility of a randomized controlled trial (RCT) protocol designed to evaluate the impact of the SC as an eHealth intervention aimed to improve physician-delivered dietary advice on sodium reduction among patients with hypertension in primary care. The findings will inform a phase 3 trial (a fully powered RCT) to determine the efficacy of

the SC on quality of care provided by physicians to their patients requiring sodium reduction. To develop and integrate successful health behaviour interventions, there is an incremental and iterative process recommended to build a body of evidence of the feasibility of the intervention, efficacy and effectiveness of the intervention and the translation and implementation into real world settings (Gitlin, 2013). Formative work was required prior to implementing the RCT protocol to determine protocol feasibility, thus three studies were conducted as part of this thesis to inform this process. These studies encompassed components of the first 3 phases of the Translation Framework from Research to Practice: the *discovery phase* of identifying the clinical problem and current evidence, *phase 1* of determining the feasibility and acceptability of the intervention, and *phase 2* in conducting an initial test of the intervention through a pilot study (Figure 1).

Figure 1. Translation Framework from Research to Practice (Gitlin, 2013)



1.2 Overview of this Thesis

The principal chapter in this thesis is **Study 3 (Chapter 6),** which was a multi-clinic, parallel RCT pilot study that was conducted to determine the overall feasibility of study protocol and implementation, and a preliminary examination of the efficacy of the SC on exploratory outcomes of quality of care and physician self-efficacy. Process, resources, management and scientific feasibility outcomes were assessed to determine the overall feasibility of the study protocol. Exploratory objectives were also examined and included: i) the frequency, type and length of physician dietary sodium advice, and ii) physician self-efficacy when providing the advice.

Two studies (Chapters 4 and 5) in this thesis focus on the development and validation of outcome measurement tools to assess these exploratory objectives, which are to be the primary objectives of a phase 3 efficacy trial of the SC intervention, and were required for implementation of the RCT protocol in the feasibility study in Chapter 6. These studies provided formative steps in this research as currently there are no measurement tools in the literature to measure quality of brief sodium reduction advice and physician self-efficacy in providing this advice.

The purpose of **Study 1 (Chapter 4)** of this thesis was to develop and validate a tool to assess quality of dietary advice, the Sodium Advice Quality (SAQ) Score, an outcome measure to collect data on the frequency, type and length of sodium reduction advice provided to patients with hypertension needed for study 3. This study was conducted prior to the initiation of study 3. *Stage 1* of Study 1 determined face and

content validity of the SAQ Score by using a sample of experts in nutrition, cardiovascular disease, medicine and survey development. *Stage 2* of the study determined the construct validity of the SAQ Score in a parallel randomized trial among patients with hypertension who received either high-quality or low-quality sodium reduction advice provided by a healthcare professional. This outcome measure tool is needed for a phase 3 randomized controlled trial to determine the effectiveness of the SC in its ability to assist physicians in providing higher quality sodium reduction advice, defined by frequency, type and duration of advice.

Study 2 (Chapter 5) of this thesis included the adaptation and validation of a tool to measure physician self-efficacy in providing sodium reduction advice. As self-efficacy is noted to be an internal factor for physicians to provide care, it is important to look at the effect of the SC on physician self-efficacy in providing sodium reduction counselling and advice in a phase 3 RCT. This tool underwent face and content validation with experts in nutrition, medicine and survey development. Prior to this study, no current tool measured the self-efficacy of physicians in providing sodium reduction counselling, specifically. The need for self-efficacy to be measured using a domain specific tool has been noted in the literature, justifying the need for the Perceived Self-efficacy of Sodium Counselling (PSSC) Scale development and validation, required prior to conducting the feasibility of a phase 3 RCT (Study 3 of this thesis), as well as the phase 3 RCT trial itself.

CHAPTER 2.0: LITERATURE REVIEW

This is a narrative literature review that was conducted to identify current literature on sodium, its role in hypertension, interventions targeting sodium reduction as a part of hypertension management, and how electronic health (eHealth) tools may assist in its management. This literature search was conducted using multiple search engines, including Scholar's Portal, Pubmed and Google Scholar between November 2016 to May 2019. Articles were included if they were less than fifteen years old, or if they contributed valuable data that had not since been updated, with Canadian literature preferred.

2.1 Hypertension

Hypertension (HTN), or high blood pressure, is defined as a blood pressure reading of greater than 140 mmHg systolic blood pressure (SBP) over 90 mmHg diastolic blood pressure (DBP) (Nerenberg et al., 2018). There is strong evidence that excess intakes of sodium over the Chronic Disease Risk Reduction (CDRR) level of 2300mg per day is a causal factor in the development of hypertension (Collaborators, 2019; The National Academies of Science Engineering and Medicine, 2019). The mechanisms by which excess dietary sodium intake causes hypertension is not fully understood, however the influence on changes to cardiac output and total peripheral resistance, through alterations to renal function, hormones, the vasculature, heart and sympathetic outflow, are known to be involved (Farquhar et al., 2015). Smooth muscle in the peripheral vasculature expands with increased dietary sodium intake, as sodium increases extracellular volume, and therefore cardiac output; prolonged consumption of excess sodium has been linked with increased arterial stiffness, resulting in increased blood

pressure (Todd et al., 2010); impaired hormonal responsiveness of the renin-angiotensin-aldosterone system is connected to a blood pressure response when exposed to excess sodium load (Farquhar, Edwards, Jurkovitz, & Weintraub, 2015; Stanhewicz & Kenney, 2015) and; high dietary sodium intakes can also cause sympathetic neural responses resulting in increased outflow and therefore increased blood pressure (Farquhar, Wenner, Delaney, Prettyman, & Stillabower, 2006). Therefore, dietary sodium plays a large role in the regulation and management of blood pressure, and is therefore a modifiable risk factor for hypertension (Aburto et al., 2013; He et al., 2013; Mozaffarian et al., 2014).

Hypertension is the most significant modifiable risk factor for the development of cardiovascular and cerebrovascular diseases, which are the 2nd and 3rd leading causes of death in Canada (Aburto et al., 2013; Bromfield & Muntner, 2013; Hornsten et al., 2016; Statistics Canada, 2017). Hypertension currently impacts 22.6% of Canadian adults, which is over 6 million individuals, and is projected to affect 29.2% of the global population in 2025 (Padwal et al., 2016; World Health Organization, 2013b). Alarmingly, lifetime incidence of developing high blood pressure by middle age is estimated at 90% (Vasan et al., 2002). Consequently, the costs associated with hypertension are significant at an estimated $13.9 billion per year, 10.2% of total healthcare spending (Forouzanfar et al., 2017; Weaver et al., 2015). By 2020, hypertension is expected to cost the Canadian healthcare system $20.5 billion due to demographic changes (responsible for 52% of increase), increasing prevalence (16%), and increasing per patient costs (32%) (Weaver et al., 2015). Since the early 1990's, hypertension awareness has improved in Ontario, increasing from 13% in 1992 to 66% in 2006 and to 68% in 2013, which is largely due to efforts to improve physician and public awareness about the importance of blood pressure

(Leenen et al., 2008; Padwal et al., 2016). However, the health and economic burden of hypertension will continue to increase steadily until appropriate prevention and control measures are implemented.

There are several known risk factors attributed to the development of hypertension. Prevalence increases with age, with 70% of older adults (>60 years old) having a diagnosis of hypertension, compared to 32% of their younger cohorts (40 to 59 years old) in North America (Mozaffarian et al., 2015). This increasing risk is related to weight gain, vascular stiffness, increased sedentary behaviour in old age and other biological changes that occur with aging (Buford, 2016; Sun, 2015). However, the risk of developing hypertension is not limited to older adults alone. A recent analysis of common, current risk factors among Canadian adults aged 20-79 years of age were recently identified and include sedentary behaviour, being overweight or obese, a diagnosis of diabetes mellitus, chronic kidney disease in women, and a poor quality diet with a consumption of less than 5 servings of fruit and vegetables/day (Leung A., 2019). Other well known risk factors include being male, a family history of premature cardiovascular disease, dysglycemia, smoking, dyslipidemia, stress, and excess sodium (Nerenberg et al., 2018). Leung et al. (2019) did not assess the impact of these risk factors, including dietary sodium on hypertension incidence; however, high dietary sodium intakes are well evidenced to be a major modifiable risk factor for the development of hypertension as described in Section 2.2 (Aburto et al., 2013; He et al., 2013; Mozaffarian et al., 2014).

To address some of these risk factors, the Hypertension Canada guidelines recommend several health behaviour modifications for the prevention and management

of hypertension (Table 1). Importantly, dietary education is listed as one of the key health behaviour management strategies, with a specific focus on sodium. These evidence-based guidelines recommend a sodium intake lower than the 2300 mg/day recommended for a healthy population, instead recommending an intake of <2000 mg/day for both the prevention and management of hypertension (Nerenberg et al., 2018). These recommendations are in alignment with the WHO's aim to reduce the prevalence of chronic diseases (World Health Organization, 2012).

Table 1. 2018 Hypertension Canada Guidelines - Health behaviour management recommendations

Health Behaviour	Guideline	Effect on BP
A. Physical Activity	• 30-60 minutes of moderate intensity dynamic exercise (4-7 days/week) • Activities of daily living	SBP by 4-9 mmHg
B. Weight Reduction	• Body mass index (BMI) target of 18.5-24.9 • Waist circumference target of <102cm (male), <88cm (female)	
Overweight individuals	• Advise to lose weight • Strategies should include multidisciplinary approach (dietary education, increased physical activity, behavioural interventions)	5-20 mmHg per 10-14 kg weight loss
C. Alcohol Consumption	• Limit alcohol to ≤2 standard drinks/day; ≤14 per week (male), ≤9 (female)	SBP by 2-4 mmHg
D. Diet Dietary Approaches to Stop Hypertension (DASH) diet:	• Emphasize diet high in fruit and vegetables, low fat dairy products, whole grain foods (high in fibre), plant-based protein	SBP by 4.6; DBP by 2.6 mmHg
E. Sodium	• **≤2000 mg/day (or 5 g salt/87 mmol sodium)**	**SBP by 10-11 mmHg**
F. Calcium and Magnesium	• Supplementation not recommended	
G. Potassium	• Increase to reduce BP (if not contraindicated)	SBP by 3.49 mmHg; DBP by 1.96 mmHg
H. Stress management	• Should be considered if individual may have stress as a contributing risk factor	Variable

(Chobanian et al., 2003; Nerenberg et al., 2018; Simces, Ross, & Rabkin, 2012)

2.2 Dietary Sodium and Health Outcomes

Sodium intakes over 2000 mg/day is a significant causal contributor to high blood pressure (Aburto et al., 2013; He et al., 2013; Mozaffarian et al., 2014; Zhang et al.,

2013). A systematic review and meta-analysis found a reduction in systolic blood pressure of −4.18 mm Hg (95% confidence interval (CI) −5.18 to −3.18, P<0.001) and −2.06 mm Hg (−2.67 to −1.45, P<0.001) diastolic blood pressure with a reduction of sodium from 3800 mg/day (9.4 g salt/day) to an 1800 mg sodium/day (4.4 g salt/day) intake among individuals with normal blood pressure. An even greater decrease in systolic and diastolic blood pressure was seen with the reduction to 1800 mg sodium/day in individuals with hypertension; a decrease of -5.39 mmHg systolic blood pressure (95% CI -6.62 to -4.15, p<0.001 and -2.82 mmHg diastolic blood pressure (95% CI -3.54 to -2.11, p<0.001) (He et al., 2013). Meta-regression showed those with hypertension had a significant reduction of 10.8 mm Hg systolic blood pressure (3.5 to 18.2, P<0.01) with a reduction to 2400 mg (6 g salt/day), respectively, when other risk factors (age, ethnic group and blood pressure status) were accounted for (He et al., 2013). Other literature also supports a sodium and blood pressure dose-response in both individuals with and without hypertension, demonstrating a linear association between dietary sodium and blood pressure (He et al., 2013; Mozaffarian et al., 2014; National Academies of Sciences, 2019). As well, the higher the baseline blood pressure is, the greater the blood pressure reduction associated with sodium reduction, with no evidence to support that various subgroups such as sex and age benefit differently (National Academies of Sciences, 2019). Importantly, reduction of dietary sodium has not been found to have adverse effects in rigorous methodological studies (Aburto et al., 2013; He et al., 2013; National Academies of Sciences, 2019).

2.3 Sodium and Hypertension

Sodium is an essential nutrient required for regulation of extracellular fluid volume, muscle contractions, nerve transmission, maintenance of acid-base balance and regulation of cell function, organ perfusion, arterial pressure, and blood volume (Chapman, Qureshi, & Kai, 2013; Farquhar et al., 2015; Geerling & Loewy, 2008; Stolarz-Skrzypek, Bednarski, Czarnecka, Kawecka-Jaszcz, & Staessen, 2013). The regulation of sodium in the body is tightly controlled by neurohumoral mechanisms that alter renal sodium and fluid reabsorption, primarily stimulated by changes in the extracellular fluid volume and sodium concentration (Stanhewicz & Kenney, 2015). For example, under normal conditions a drop in blood pressure resulting from a change in cardiac output or peripheral vascular resistance triggers the release of vasopressin by the pituitary gland, stimulating renal fluid reabsorption in response to the decrease in blood pressure. At this time, the renin-angiotensin-aldosterone system is also activated to restore blood volume through the resorption of sodium in the proximal renal tubules, systemic vasoconstriction and stimulation of the thirst sensation. It is estimated that <500mg is required to maintain homeostasis in adults, as obligatory losses of sodium through urine (the primary excretion) and sweat are only 100-200mg/day due to tight homeostatic control of sodium (The National Academies of Science Engineering and Medicine, 2019).

Studies examining the relationship between a high sodium intake and high blood pressure suggest the mechanisms are complex and interconnected (Drenjancevic-Peric et al., 2011). Although research to date has not been able to fully explain these mechanisms, they are known to involve alterations in renal function, regulation of fluid by

neurohormonal mechanisms, the vasculature, the heart, genetic mechanisms and/or central sympathetic outflow (Farquhar et al., 2015). Impaired hormonal responsiveness of the renin-angiotensin-aldosterone is linked to a blood pressure response when exposed to excess or limited sodium load (Farquhar et al., 2015; Stanhewicz & Kenney, 2015). Some individuals are more sensitive to sodium than others: older adults, those with hypertension, African American ethnicity and those with chronic disease such as chronic kidney disease and heart failure (Elijovich et al., 2016). However, there is no standardized, reliable method of diagnosing sodium sensitivity therefore the characterization of such individuals is challenging. Furthermore, since those with normal blood pressure levels also benefit from sodium reduction, the public health implications of focusing efforts on sodium reduction in only those with salt sensitivity are not justified at this time.

At the population level, a reduction in dietary sodium is estimated to decrease the prevalence of hypertension by 30%, which would equate to 1 million fewer Canadians with the diagnosis, 23% fewer individuals requiring medications to control blood pressure and a savings of $430 million per year (Joffres, Campbell, Manns, & Tu, 2007). The long-term effect of reduced blood pressure resulting from decreased sodium intake (supported by dietary and behavioural counselling to identify sources of sodium, self-monitor intake and select low sodium options), has resulted in a 25% reduction in cardiovascular events 10-15 years later, compared to controls (RR 0.75, 95% CI 0.57 to 0.99, P=0.04) (Cook et al., 2007). Intensive blood pressure lowering provides greater vascular protection than standard regimes and, in addition to lowering risk reduction for cardiovascular events, has also been found to reduce the rate of stroke by 22% (Xie et al.,

2016). Therefore, the impact of excess dietary sodium on health outcomes makes dietary sodium an area of public health concern in Canada, particularly in light of the high amounts of sodium consumed by Canadians.

2.4 Sodium Intakes of Canadians

On average, Canadians consume an estimated 2670 mg of sodium per day, with all age and gender groups consuming over the recommendations (Arcand et al., 2011; Canada, 2018; Shi, DeGroh, Morrison, Robinson & Vardy, 2011). Of concern, it is also speculated that Canadians with hypertension have higher sodium intakes (~3000mg) compared to those without, even though more individuals with hypertension are concerned about their sodium intakes compared to those with normal blood pressure (Arcand et al., 2013; Shi et al., 2011 ; Zhang et al., 2013).

Dietary sodium is derived from three main sources: commercially packaged and prepared foods, naturally occurring sodium in foods, and discretionary salt (i.e. salt added at table or during cooking) (Zandstra, Lion, & Newson, 2016). Only 11% of dietary sodium is estimated to come from added salt (Harnack et al., 2017). However, over 70% of dietary sodium comes from packaged and processed foods (Anderson et al., 2010; Harnack et al., 2017; Mattes & Donnelly, 1991), with the highest current contributors of processed foods for Canadians being bread products (19.5%), mixed dishes (19.4%) and processed meats (11.2%) (Health Canada, 2018). These data are also supported in other research (Fischer, Vigneault, Huang, Arvaniti, & Roach, 2009b; Kirkpatrick, Raffoul, Lee, & Jones, 2019). Interestingly, these main sources of sodium have remained consistent over the past ten years, and are similar in consumption across both high and

low income groups according to 2015 Canadian Community Health Survey (CCHS) data (Kirkpatrick et al., 2019).

Contradictory to what is known about the main sources of sodium, there are large misconceptions and a lack of knowledge about sodium among Canadians, as well as globally. Concerningly, 87% of individuals in an online international study (involving Germany, Austria, United States of America, Hungary, India, China, South Africa, and Brazil) conducted to derive knowledge on salt intake and associated behaviours among a global population were not aware, or incorrectly reported sodium recommendations (Newson et al., 2013). Many believe that a lack of salt added at the table or during cooking equates to a low sodium intake. In a Canadian survey, only 41% of Canadian participants believed that their personal sodium consumption was 'too high' due to this misconception, a finding also consistent with other countries (Newson et al., 2013). Canadians who had actively been trying to limit sodium were found to not actually be restrictive of high sodium foods as they believed they were consuming low amounts of sodium since no salt was added to their food (Arcand et al., 2013). This misconception is understandable as it can be difficult for individuals to successfully monitor their daily sodium intake. Fortunately, due to a widespread knowledge of the health impact of too much sodium there is interest to know which foods are the highest contributors of sodium in their diet (Newson et al., 2013). Individuals want to acquire this information from food labels and healthcare professionals (57%) rather than food retailers and friends/family (14%, $p<0.001$) (Newson et al., 2013). This emphasizes the importance of developing and implementing lifestyle interventions on the individual level, delivered with support from Canadian's healthcare providers, including registered dietitians and physicians.

2.5 Current Sodium Reduction Interventions

To help lower population sodium intakes, sodium reduction policies and programs have been developed and implemented both nationally and globally. In 2016, the WHO issued nine global targets for chronic disease prevention. This included new guidance on dietary sodium in order to meet the global action plan of a 30% reduction in sodium intake (WHO, 2016). To successfully facilitate this sodium reduction, action is required at both population and individual levels, and needs to include individuals, civil society, healthcare providers and their professional societies, academia, public health agencies and governments (WHO, 2016).

2.5.1 Population level sodium reduction

Population level strategies to decrease sodium intakes include consumer education, food labelling, updating national dietary guidelines and reformulation of processed foods by food manufacturers (WHO, 2012). A recent systematic review of current interventions to reduce sodium consumption found that the main population level interventions for sodium reduction implemented globally were 1) product reformulation, consisting of both mandatory and voluntary reductions, 2) health promotion campaigns, 3) mandatory labelling of sodium content on pre-packaged foods, and 4) taxation or incentives to encourage moderation of the amount of sodium in processed foods by the food industry (Trieu et al., 2015). In 2010, Canada developed Canada's Sodium Reduction Strategy which recommended research and surveillance on sodium in Canada, sodium education to the public and key stakeholders, and voluntary sodium reduction in packaged foods as well as other regulatory measures related to food labelling and regulatory processes for additives (Sodium Working Group, 2010). However, industry

has come up short with only 16.2% of food categories showing significantly reduced sodium levels in 2013, and minimal additional progress by 2016 (Arcand et al., 2016; Health Canada, 2018).

Health Canada has also implemented two education and awareness strategies to date to help reduce sodium intake on the population level. These included a Nutrition Facts education campaign to help consumers inform their food choices, and an Eat Well campaign aimed at educating Canadians to understand the adverse health effects of excess sodium intakes. However, the impact of these two initiatives on individual behaviours or sodium intakes were not reported in the most recent Health Canada Sodium Report (Health Canada, 2018). The lack of effective policies and programs at the population level emphasizes the need for the implementation of supportive sodium reduction strategies at the individual level. In order for sodium reduction in Canada to be effective, individual Canadians will be required to change their food intake behaviours to consume lower sodium. Based on known knowledge deficits and misconceptions about dietary sodium among Canadians, education and counselling are required to complement population-based approaches to reduce sodium in Canada.

2.5.2 Sodium reduction interventions at the individual level

Comparatively, little work has been done at the individual level to help reduce dietary sodium. The majority of individual level interventions related to sodium reduction occur as various types of behavioural counselling interventions in primary care settings. Therefore, behavioural counselling interventions that are effective and feasible are

needed in primary care settings to assist individuals in minimizing health behaviour risks, including nutrition (Curry & McNellis, 2015).

The WHO (2016) emphasizes the importance of the role of primary care in promoting and engaging individuals in weight management, physical activity and healthy diets to address chronic disease. Patients with chronic diseases are most often seen in primary care practices, making this healthcare setting a key location to integrate these health behaviour interventions (Clarke & Hauser, 2016; Dysinger, 2013; Wolfenden et al., 2016). Registered dietitians are the experts in intensive nutrition care, however access to dietitian services is limited in primary care settings due to a low rate of referrals. Only 41.7% and 21.7% of Canadian physicians have been found to make more than 20 referrals per year in rural and urban settings, respectively (Wynn et al., 2010). This places the role of dietary counselling on physicians in many circumstances. Therefore, to ensure that patients who require dietary modifications to help manage their chronic disease receive the quality of care they need, it is essential to develop feasible nutrition counselling interventions for primary care physicians to support and implement. Physician recommendations and counselling have been consistently found to have influence on patient engagement in health behaviours, making these healthcare providers an important source of preventative health information at the individual level (Arcand et al., 2013; Kreuter et al., 2000; Pool et al., 2014). However, considering time constraints in primary care, even a brief engagement in discussion or advice about diet and barriers to lifestyle modifications is thought to be beneficial to aide in patient behaviour change (Cobb, Appel, & Anderson, 2012). It is imperative that physicians counsel their patients

on health behaviours, including dietary risk factors, in order to help prevent and treat chronic diseases such as hypertension (Cresci, Beidelschies, Tebo, & Hull, 2019).

2.6 Health Behaviour Counselling by Physicians in Primary Care

Primary care physicians have an impactful role in providing advice and counselling on health behaviours. Moderate to intensive health behaviour counselling interventions by physicians that relate to diet and physical activity have been found to have small yet effective outcomes on health markers including cholesterol, body weight, blood sugar, and blood pressure (Elliott & Cifu, 2015; Hardcastle, Taylor, Bailey, & Castle, 2008; Lin et al., 2014b; Patnode, Evans, Senger, Redmond, & Lin, 2017; Pool et al., 2014; Rose, Poynter, Anderson, Noar, & Conigliaro, 2013). Even brief messages about diet from physicians can engage patients and influence their behaviour (Pignone, Phillips, Elasy, & Fernandez, 2003).

In health behaviour counselling among patients with cardiovascular disease, smoking was the most common health behaviour advice provided to patients, with diet and physical activity advice being notably lower (Bock, Diehl, Schneider, Diehm, & Litaker, 2012). In a study of Canadian primary care physicians, more than half believed that the majority of their patients would benefit from nutrition advice, but only 19.1% of patients were actually provided with dietary counselling by their physician (Wynn et al., 2010) (Table 2). In another study, only 6.5% of physicians provided dietary advice in more than 50% of patient visits, with 72% percent of physicians providing dietary advice ≤31% of the time (Eaton, Goodwin, & Stange, 2002). However, a major consideration with this data is that the prevalence of health behaviour counselling determined in these

studies may actually be an overestimation due to the Hawthorne effect. Even still, the proportion of general practitioners and internists that provide specific sodium reduction advice has undeniably decreased significantly, as shown between 2010 and 2015 (Quader, Cogswell, Fang, Coleman King, & Merritt, 2017). Not only are these rates of dietary counselling low, there is also a trend of physicians providing counselling on other supportive health behaviours for hypertension prevention and management compared to dietary advice (<41%), such as alcohol (72%), physical activity (70%), smoking (74%), and weight reduction (81%) (Table 2) (Bock et al., 2012). Finally, two studies showed that physicians are more likely to initiate discussion around weight and smoking (compared to diet), while the patient is more likely to initiate discussions around diet (Milder, Blokstra, de Groot, van Dulmen, & Bemelmans, 2008; Noordman, Verhaak, & van Dulmen, 2010). Despite the low rates of implementation of dietary advice in primary care, dietary interventions for hypertension are considered a priority by the majority of physicians (82.5%) (Dash, 2019). However, this does not appear to translate into practice. A review of literature examining the prevalence of health behaviour counselling, summarized in Table 2, shows that counselling, especially dietary counselling, is universally provided at rates of less than 44% of patient visits. This is across multiple countries, patient groups and using various methods of data collection.

Table 2. Prevalence of Behavioural Counselling

			Type of Behavioural Counselling		
	Patient Population	Methodology	Physical Activity	Diet	General lifestyle
(Eaton et al., 2002) (US)	All patients	Direct observation of physician visits	N/A	24% (CVD related appointments) 31% (HTN related appointments)	N/A
(Mellen, Palla, Goff, & Bonds, 2004) (US)	Individuals with hypertension	National Hospital Ambulatory Medical Care Survey (NHAMCS) data from 1999/2000 surveys)	35%	25%	N/A
(Ma, Urizar, Alehegn, & Stafford, 2004) (US)	Individuals with elevated cardiovascular disease (CVD) risk	NHAMCS data from 1992/2000 surveys)	<30%	33%	N/A
Anis et al. (2004) (US)	All patients	Direct observation	20%	25%	N/A
Milder et al. (2008) (The Netherlands)	Patients with hypertension	Video recordings of physician visits (HTN related)	N/A	12% of patient provided specific advice	36%
Wynn et al. (2010) (Canada)	N/A	Physician survey	N/A	19.1%	N/A
Smith et al. (2011) (US)	Adults with and without disease	Nationally representative survey	~50%	43.4%	Specific to weight control: 38.7%
Al-Muammar (2012) (Saudi Arabia)	All patients	Physician self-reported survey	N/A	40.9% provided unknown disease specific advice	Specific to weight control: 22.2%
(Ahmed, Delgado, & Saxena, 2016) (US)	All individuals	2000/2011 National Health Interview Survey (NHIS) data	N/A	32.6%	N/A

2.7 Quality of Nutrition Counselling

When primary care physicians do provide dietary counselling it is often considered to be minimal. The amount of time spent on dietary counselling is reported to

be only an average of 55 seconds, as found in a fee for service clinic (Eaton et al., 2002). An important consideration is that the estimate is likely higher due to the Hawthorne effect (Goodwin et al., 2017). Physicians are not always able to provide sufficiently detailed nutrition advice, and advice provided to patients with hypertension is often general, likely due to time restrictions (Fang, Cogswell, Keenan, & Merritt, 2012; Kahan & Manson, 2017). The frequency of more specific advice such as 'read nutrition labels for sodium', 'eat less processed foods', and advice about foods to avoid or recommendations to reduce salt when cooking has unfortunately decreased significantly between 2010 and 2015 ($p<0.0001$). Additionally, a significant increase in the number of physicians who are not providing advice has also been seen ($p=0.001$) (Quader et al., 2017). Barriers to the provision of dietary advice, as examined within Section 2.8, has been documented in the literature, however, more needs to be done to understand where care is lacking, and evaluate potential interventions that can be developed to facilitate a higher quality of care.

Providing high-quality care to patients is vital in successfully preventing and managing chronic disease. Quality of care has been defined as '*the degree to which health services for individuals and populations increase the likelihood of positive health outcomes and are consistent with current professional knowledge*' (Hrisos et al., 2009). Clinical quality of care relates to: i) the interactions between healthcare provider and their patient and the process of care (shared decision making), or how well healthcare services are provided to patients (clinical processes), and ii) the ways in which the inputs from the healthcare system transform into health outcomes (Donabedian, 2005; Hanefeld et al., 2017). As discussed previously, high sodium intakes are linked with poor health

outcomes, including high blood pressure which is a risk factor for the development of cardiovascular, cerebrovascular, and renal disease (O'Donnell et al., 2010; Yoon et al., 2018). However, health outcomes can be poor measures of clinical quality of care as there are many other factors that also contribute to their development, and they also have an inability to examine specific management and care provided to the patient (Lilford, Brown, & Nicholl, 2007). Clinical processes, like patient care, on the other hand are directly attributed to healthcare provider behaviour (Lilford et al., 2007). Their measurement provides a critical starting point in developing methods and interventions to improve care received by patients from their healthcare provider (Hanefeld et al., 2017). Therefore, an evaluation of clinical processes in hypertension management is vital in determining where gaps lie in health behaviour counselling related to this chronic disease. This includes evaluation of sodium reduction advice in order to develop and implement meaningful and efficacious interventions to assist physicians or other healthcare providers in providing the highest quality of care in hypertension management.

2.8 Physician Action to Provide Behavioural Counselling

In order to improve the quality of care provided by physicians for chronic disease management, such as hypertension, as stated in section 2.5, it is necessary to examine and understand internal and external factors, and barriers and facilitators that impact implementation of dietary advice. This knowledge is needed in order to develop effective interventions to improve physician dietary counselling in primary care settings.

2.8.1 Physician internal factors related to the provision of dietary counselling

In physician-patient clinical encounters, physicians are in a position where they need to consider, or are influenced by, internal factors as part of their decision making on what care to provide for each patient. These internal factors include specific **physician characteristics** including: gender, specialty, age and length of time in practice, knowledge and training and perceived self-efficacy.

1. Gender. Female physicians are more likely to provide general lifestyle counselling, specific guidance on diet to all patients and referrals for further evaluation and management (Bertakis, 2009; Smith et al., 2011).

2. Specialty. General practitioners and cardiologists are 1.3 and 1.8 times more likely to provide diet counselling than other specialties (Ma et al., 2004; Smith et al., 2011).

3. Age and length of practice. Canadian physicians between the ages of 45-64 years, or those who have been out of school longer (>10 years) and therefore further along in their career with more experience are more likely to counsel their patients on preventative health risk behaviours (alcohol, smoking, physical activity, pedometer use, weight management, diet etc.) compared to those younger than 45 years ($p<0.001$) (Crowley et al., 2015; Smith et al., 2011).

4. Knowledge and training. A lack of knowledge and training is a relevant barrier commonly found in the literature (Al-Muammar, 2012; Kolasa & Rickett, 2010; Kushner, 1995; Lugtenberg, Burgers, Besters, Han, & Westert, 2011; Mogre, Aryee, Stevens, & Scherpbier, 2017; Quader et al., 2017). A large majority of Canadian physicians (82%) reported that they considered their nutrition education to be inadequate, and 65.8% of

physicians in an unrelated study wished they had learned more about it during their residency (Dash, 2019; Wynn et al., 2010). A Canadian study of the perceptions of medical students indicates that the education they receive prepares them to counsel patients on basic nutrition concepts and the role of nutrition in disease prevention, however, they did not feel prepared to discuss nutrition as part of disease treatment and identification of credible sources of nutrition information (Gramlich et al., 2010). This is likely to contribute to physician reports of low self-efficacy in providing nutrition care (Kushner, 1995; Mogre et al., 2017; Singer, Izhar, & Black, 2004).

5. Self-efficacy. Not surprisingly, physicians who have higher motivation and self-efficacy in counselling tend to provide higher rates of health behavioural counselling (Singer et al., 2004). *Self-efficacy* is a key influence on behaviour, and can be a barrier to the provision of dietary counselling when lacking (Bandura, 1997). A lack of training in nutrition and behavioural modification skills, and a lack of knowledge are associated with low self-efficacy, which has been widely reported to affect a physician's ability to advise patients about nutritional topics or to improve patients' diet (Al-Muammar, 2012; Cabana et al., 1999; Chiriboga, Ockene, & Ockene, 2003; Kolasa & Rickett, 2010; Kushner, 1995; Lugtenberg et al., 2011; Wynn et al., 2010). A common trend is that physicians are open to discussing diet with their patients in the management of their chronic disease, but they are uncomfortable giving specific nutrition advice (Wynn et al., 2010). Even when physicians are knowledgeable in the area of nutrition, there are challenges to practically applying that knowledge with their patients (Cabana et al., 1999), which may explain the poor compliance to clinical guidelines that is seen in the literature. Typically, physicians

are significantly more comfortable assessing medication adherence (77%) compared to dietary adherence in sodium restriction (14.2%) (Bell & Kravitz, 2008).

2.8.2. Physician external factors related to the provision of dietary counselling

External factors consist of socioeconomic factors, including physician interaction with the healthcare system, the physician-patient relationship and patient factors. There are a number of **patient-related characteristics** that weigh in on the physician's decision to provide dietary counselling.

1. Patient ethnicity. Physicians have been found to provide dietary counselling at different rates for patients of certain ethnic groups (e.g. Hispanic, Asian and African-American 1.2-1.7 times more likely to receive counselling) (Lopez, Cook, Horng, & Hicks, 2009; Ma et al., 2004).

2. Patient diagnoses. Physicians are more likely to provide dietary counselling with patients who have diabetes, obesity, cardiovascular disease or dyslipidemia, and for those who are newly diagnosed with hypertension or patients with multiple cardiovascular comorbidities. (Corsino, Svetkey, Ayotte, & Bosworth, 2009; Eaton et al., 2002; Mellen et al., 2004; Milder et al., 2008; Sinclair, Lawson, & Burge, 2008). They are also more likely to provide behavioural counselling and specific advice to patients with obesity and weight related chronic disease diagnoses (Goldberg, Cho, & Lin, 2019; Smith et al., 2011)

3. Patient age and gender. Physicians are 1.2-1.3 times more likely to provide diet counselling with patients that are >74 years of age (Bell & Kravitz, 2008; Goldberg et al., 2019). The decision to provide dietary counselling may also be based on the gender

of the patient, as female patients have been found to be more focused on preventative services (p=0.001), and therefore may prompt this care provision (Bertakis, 2009).

4. Patient needs and preferences. There are also the perceptions that patients prefer medication management as opposed to lifestyle management (46.8%), and patient concern over more immediate health issues as key external factors that influence physician provision of dietary counselling (Quader et al., 2017). The reason for the patient visit and the physician's judgement of the appropriateness of addressing behavioural counselling have been found to be significantly associated with the provision of behavioural interventions (Laws et al., 2009).

The **physician-patient relationship** is a sociological factor that influences the decision to provide dietary counselling. The length of the professional relationship between the physician and the patient is noted to play a role in the decision-making process. However, there are mixed findings. Some studies report that the longer the physician has been providing care for the patient, the greater the likelihood of receiving dietary counselling, while others report that new patients are more likely to receive this counselling from their physician (Anis et al., 2004; Goldberg et al., 2019; Ma et al., 2004). In this case, there is speculation that when a physician is familiar with their patient's diet and physical activity, these behaviors often are omitted from discussion (Bardach & Schoenberg, 2018).

Physician interaction with the healthcare system includes a number of factors that contribute to the decision to provide dietary counselling.

1. Physician workload. This workload includes their patient caseload, which impacts the amount of time a physician has to spend per patient. *A lack of time* is one of

the most commonly cited barriers to the provision of behavioural counselling. The length of the appointment is associated with the likelihood that lifestyle factors will be discussed, with longer appointments (average 20 minutes) increasing the odds of counselling occurring compared to shorter visits (Eaton et al., 2002; Ma et al., 2004). However, hypertension related appointments have been found to be an average of 9.8 ± 4.7 minutes (range: 2.5 - 30 minutes) (Milder et al., 2008). Over 75% of physicians believed they did not have enough time to counsel patients to lower their sodium intake (Dash et al., 2019). Nutrition counselling is also more likely to occur during longer appointments, which would help explain why lack of time has continually been identified as a barrier to physicians providing nutrition advice, with physicians spending five minutes or less discussing dietary changes (Eaton et al., 2002; Kushner, 1995; Quader et al., 2017; Wynn et al., 2010). Patients with multiple comorbidities may receive less nutrition counselling than other patients as there are potentially multiple issues that require attention (Jay et al., 2015). This supports the need for effective *brief* lifestyle counselling strategies and tools for primary care providers to use (Wynn et al., 2010).

2. Lack of adequate patient education tools. This is commonly noted as a barrier to providing patients with dietary counselling, with physicians often relying on brochures to provide dietary advice (Doroodchi et al., 2008); (Quader et al., 2017).

3. Lack of compensation. This is a barrier in both fee for service and salaried clinics (Dash et al., 2019; Kolasa & Rickett, 2010; Lugtenberg et al., 2011; Quader et al., 2017; Wynn et al., 2010).

2.8.3 Facilitators to providing dietary advice

Finding effective strategies to facilitate healthcare professionals in the implementation of clinical guidelines, including health behaviour counselling, is vital to the provision of high-quality healthcare in hypertension management (Grimshaw, Eccles, Lavis, Hill, & Squires, 2012). Therefore, understanding facilitators to the successful provision of dietary counselling and advice in primary care is just as important as understanding barriers. In a recent survey among a national sample of Canadian physicians, facilitators reported were having access to a registered dietitian (84.9%), increased nutrition education in medical school (65.8%), compensation for providing dietary counselling (64.4%), an Electronic Medical Record (EMR) prompt to educate patients about diet (57.5%) and a specific app, EMR or electronic health (eHealth) tool to help educate patients about diet (80.8%) (Dash et al., 2019). Electronic health (eHealth) is noted as a promising strategy in minimizing many of these barriers to provide better quality of care, more effective and efficient care, and in encouraging shared decision making and patient self-management support through patient empowerment (Party, 2016; Stoffers, 2018).

2.9 eHealth Tools and Interventions

eHealth is defined as: '*...an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies* (Eysenbach, 2001), or in simpler terms *'eHealth is the use of information and communication technology in healthcare'* (Granja et al., 2018). eHealth tools are broadly accessible and can be

accessed in many different forms. They can include interactive websites, telehealth, online communities, mobile applications, or clinical information systems (EMRs, decision support tools, etc.), giving them the ability to reach large populations efficiently due to their widespread reach (Eysenbach, 2001; Saner & van der Velde, 2016). Importantly, they can be implemented into healthcare settings with benefits to both patients and healthcare providers as an intervention that is an increasingly efficient way to improve access and quality of care (Broekhuizen, Kroeze, van Poppel, Oenema, & Brug, 2012; Elbert et al., 2014; Inglis et al., 2010; Liang et al., 2011). In fact, eHealth interventions are recognized to have incredible potential for chronic disease prevention and management through encouragement of adoption of healthy behaviours. They are recommended by the WHO as a means to improve access to care, increase patient participation in decision making, facilitate improved healthcare provider quality of care through providing users with support, information and skills required for health behaviour change (Hanefeld et al., 2017; Kreps & Neuhauser, 2010; Noar, Harrington, & Helme, 2010; Schulz et al., 2014; Solomon, 2008). Consequently, eHealth based prevention has been implemented in primary care in many health behaviour areas, primarily targeting weight related behaviours such as physical activity and dietary behaviours, but also alcohol use and smoking, and has shown noted success compared to generic or no information (Broekhuizen et al., 2012; Kohl, Crutzen, & de Vries, 2013; Ockene, 1999; Reiff-Hekking, Ockene, Hurley, & Reed, 2005).

eHealth interventions usually incorporate effective behaviour change techniques to increase engagement and aide in self-management, and have been found to facilitate behaviour change (Kebede, Christianson, Khan, Heise, & Pischke, 2017; Plaete et al.,

2016)**.** Examples of behaviour change techniques include provision of information about health consequences, goal setting, monitoring of behavior and individualized feedback tailoring (Duff et al., 2017). Tailored feedback has been shown to increase awareness of personal behaviour patterns, personal behaviours compared to recommendations, and assisting with setting and monitoring progress towards behaviour change goals (Broekhuizen et al., 2012; de Vries & Brug, 1999). However, despite the benefits to eHealth tools, the literature supports that these tools alone are not always the sole solution to improving care of patients with chronic diseases. Patients have been found to be less likely to reduce their sodium intake unless it is explicitly recommended by their healthcare provider (Arcand et al., 2013; Kreuter et al., 2000; Pool et al., 2014). Higher attrition rates have also been found in studies of eHealth interventions due to anonymity and limited face to face contact, and when individuals have been asked to make their own action plan (Eysenbach, 2005; Van der Mispel, Poppe, Crombez, Verloigne, & De Bourdeaudhuij, 2017). This enhances the need for physician supported eHealth interventions to be used in care provided to their patients. Physician delivered health behaviour advice regarding physical activity or diet has been shown to influence older adults' health behaviours through developing strong relationships, addressing concerns and encouraging change, and providing concrete instructions (Bardach & Schoenberg, 2018). Providers are able to increase patient's confidence in their ability to make dietary and physical activity improvements, or continue with current efforts, through addressing their health concerns that were viewed by patients as barriers to change (Bardach & Schoenberg, 2018). Interestingly, when diet advice provided is brief, or not discussed at all, patients perceive this means they should continue their current health behaviours

(Bardach & Schoenberg, 2018). Tailored messaging from eHealth tools provided with brief advice has a stronger effect on health outcomes of patients compared to simply using tailored messages alone, and require only a modest amount of time during routine primary care provision (Wanyonyi, Themessl-Huber, Humphris, & Freeman, 2011). eHealth interventions that combine health behaviour counselling and health education are associated with improvements in disease-related clinical and behavioral outcomes (Hamine, Gerth-Guyette, Faulx, Green, & Ginsburg, 2015; Ockene, 1999; Reiff-Hekking et al., 2005). This informs that eHealth interventions that provide tailored messaging along with the support of healthcare professionals in the maintenance of patient health behaviour change are likely to be effective.

Although research is emerging, to date research efforts on eHealth interventions have focused more prominently on patient benefits, rather than the benefit to the provider in the care for their patients. eHealth interventions have been shown to improve communication between healthcare provider and patient, provide more patient-centered care, reduce the gap of provision of care, and show clinical management improvement and improved diagnoses, all of which contribute to the quality of care provided (George, Hamilton, & Baker, 2009; Hao et al., 2015; Hunting et al., 2015; Marzegalli et al., 2008; Palmier-Claus et al., 2013; Praveen et al., 2014; Steele Gray, Gill, et al., 2016; Steele Gray, Khan, et al., 2016). Overall, tailored eHealth technologies are well accepted or regarded by physicians, as they can be helpful in detecting, assessing and managing patient symptoms, and can save time (Boyce, Browne, & Greenhalgh, 2014; Carey et al., 2015). The ability of tailored eHealth tools to minimally impact practice was also appreciated, as was their ability to provide real time synthesis and analysis of patient

data, eHealth tools also have the ability to remind physicians to counsel, and provide reminders and linked resources to facilitate structured, evidence based approaches to counselling (Krist et al., 2008; Rattay, Ramakrishnan, Atkinson, Gilson, & Drayton, 2009). Use of an eHealth intervention in cardiovascular disease care has demonstrated increased healthcare provider self-efficacy, improved workflow and appropriate management of patients (Praveen et al., 2014). However, these studies have focused on quality of care of telemedicine, mobile health (mHealth) and short message service (SMS) messaging eHealth interventions, rather than internet delivered or EMR incorporated interventions.

Therefore, based on current evidence, brief eHealth interventions may increase nutrition counselling prevalence, improve physicians' understanding of individualized patients' diets, and subsequently increase physicians' nutrition knowledge and the quality of care provided (Bonilla et al., 2015). However, little research has been completed to date to determine the effectiveness and impact of an eHealth intervention on the quality of care provided by primary care physicians regarding dietary sodium guidelines in the management of hypertension.

2.10 The Sodium Calculator eHealth Intervention

A limited number of nutrition eHealth tools currently exist, with focuses on assessment of overall nutrition risk; dietary fat; fruits and vegetable intake; and infant nutrition (Arcand, Abdulaziz, Bennett, L'Abbe M, & Manuel, 2014; Helle, Hillesund, Wills, & Overby, 2019; Keller, 2016; Keller, Goy, & Kane, 2005; Norman et al., 2007; Plaete et al., 2016; Randall Simpson, Keller, Rysdale, & Beyers, 2008). Currently,

one Canadian specific sodium eHealth assessment tool exists in the literature, the Sodium Calculator (SC), which has the potential to aide in the prevention and management of hypertension in primary care settings (Arcand et al., 2014). Other sodium screening tools exist, however they are either paper based or are not publicly available (Mason et al., 2014). The SC, a web-based eHealth tool, was created with the potential to assist patients in the self-management of reducing their sodium intake and in minimizing many of the barriers that prevent healthcare providers from implementing behavioural interventions in sodium reduction. It has been found to be effective in improving user sodium knowledge, attitudes and intended behaviours (Jefferson et al., 2019). Other types of technology based sodium reducing interventions have been found to be effective in sodium reduction, therefore the SC has the potential to have an impact on reducing sodium intakes of Canadians (Ali et al., 2019).

The SC was developed considering the sodium content of foods from an up to date food database, as well as sources of sodium and portion sizes consumed by Canadians in the Canadian Community Health Survey (Health Canada, 2018; Fischer, Vigneault, Huang, Arvaniti, & Roach, 2009a; Schermel, Emrich, Arcand, Wong, & L'Abbe, 2013). It is a specialized health assessment and education tool that consists of both diagnostic assessment and personalized feedback based on the individualized sodium intake information that was entered into the tool. This real-time feedback is tailored to the individual and identifies the estimated amount of daily sodium consumed, how the user's intake compares to the sodium recommendations for their age and sex, and main sources of sodium in their diet. This has benefit over traditional methods of sodium assessment including time consuming and burdensome 24-hour urine collections, food

records, food recalls and food frequency questionnaires. It has been validated against food records ($r=0.60$, $p<0.001$), identifying its potential as a valid, rapid sodium intake measure to help healthcare providers in assessing sodium risk in patients with hypertension in fast-paced primary care settings at point of service (Arcand et al., unpublished).

The SC also has the potential to be used as a clinical decision support system (CDSS) tool by healthcare professionals to determine pertinent education and care plans for their patients. CDSS tools are effective at improving clinical practice, and can also help facilitate physician adherence to guidelines and in facilitating preventative care counselling (Jamal, McKenzie, & Clark, 2009; Kawamoto, Houlihan, Balas, & Lobach, 2005; Kronish et al., 2016; Lobach et al., 2012; Tang et al., 2012). It is also established that when patients record their dietary intake, physicians can target and improve the quality of their nutrition advice (Bonilla et al., 2015). Therefore, the SC has the potential to benefit physicians in the dietary management of their patients with hypertension.

Additionally, the SC has the potential to minimize many barriers to the provision of dietary counselling and advice. The calculator takes <5 minutes to complete and can be strategically implemented in practice by having patients complete the tool in the waiting room or exam room prior to their appointment. With the patient data synthesized and analyzed rapidly, the physician simply needs to review the feedback at point of service, estimated to take <30 seconds. This may minimize the barrier of limited time in fitting behavioural interventions into appointments in primary care. As mentioned, the SC provides the user with tailored feedback, shown to increase the likelihood of patient engagement, and hypothesized to help improve patient non-adherence. Interventions that

incorporate tailoring provide more relevant feedback, less redundant information, and are more likely to be processed and remembered by the individual (Brug, Oenema, & Campbell, 2003; Lustria, Cortese, Noar, & Glueckauf, 2009; Lustria et al., 2013; Noar, Benac, & Harris, 2007). It has been shown that an individual is more likely to engage in the desired behavior with this personalized feedback function due to the relevance to the individual (Lustria et al., 2009). Thus far it has been effective in binge drinking, general diet and smoking interventions (Lustria et al., 2009), and specifically in patients targeting sodium reduction (Parekh, Vandelanotte, King, & Boyle, 2012).

The SC has shown to improve user knowledge, attitudes and intended behaviours by providing information on main sources of sodium, and will provide links to relevant sodium resources, providing physicians with adequate patient education tools at time of use. Finally, the SC has the potential to assist physicians in prioritizing whether sodium reduction needs to be discussed with their patient by screening the patient for the consumption of too much or an adequate amount of sodium. It can also direct the physician in discussing strategies that are most appropriate to the patient based on main sources of sodium in their diet. It is hypothesized that use of the SC may increase physician confidence/self-efficacy in providing dietary counselling by directing the physician to discuss what is most relevant to the patient, and therefore potentially increase the facilitation of sodium reduction discussion between healthcare providers and their patients, potentially improving quality of care.

2.11 Summary

The current literature has focused on prevalence of physician behavioural counselling, including nutrition counselling specifically, factors associated with and barriers to the provision of behaviour counselling, assessment of the type of nutrition advice provided, and the effectiveness of eHealth interventions on patient and provider outcomes; however, little research has been conducted specifically on the effectiveness of eHealth interventions on the facilitation of dietary sodium advice by physicians. eHealth interventions that are evidence-based and designed by experts have been shown to effectively improve patient outcomes, health behaviours, self-management of chronic morbidities (McLean et al., 2016), and are highly supported by Canadian physicians for the monitoring and provision of dietary advice (Dash et al., 2019). eHealth interventions that focus on diet have the potential to support physicians in improving the quality of advice provided to patients, however this has not been extensively examined in the literature. In other words, there has been minimal work completed to understand how eHealth tools, specifically a dietary sodium screening eHealth tool, can enhance the quality of care from healthcare providers in hypertension management. No previous work has been developed to assess the quality of general, *brief* dietary counselling and/or dietary sodium reduction, as well as provider confidence in providing brief dietary sodium advice. As healthcare evolves, and new tools and health behaviour interventions are developed to assist healthcare providers in improving health outcomes of their patients, it is essential that the quality of care provided when implementing these interventions is examined.

2.12 Next Steps

Behavioural interventions implemented into primary care have their own unique barriers, supporting the need to incrementally and iteratively develop and implement into this practice setting (Burke & Gitlin, 2012). This process is also recommended in order to embed and normalize the intervention into the intended practice setting for long-term adoption (Gitlin, 2013). The studies incorporated in this thesis were designed to develop and pilot a protocol to feasibly conduct a future large scale randomized controlled trial to assess the effectiveness of the SC in improving the quality of dietary sodium reduction advice provided by physicians, and their self-efficacy in providing this advice. This thesis sets up this research through implementation of the first 3 phases of Gitlin's (2013) continuum to implement new interventions. This helped guide development of the specific objectives of this thesis, found in Chapter 3.

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CHAPTER 3.0: OVERALL THESIS OBJECTIVES

Study 1: To develop and validate a tool that can be administered to assess quality of dietary advice in primary care settings [Sodium Advice Quality (SAQ) Score].

a. To assess face and content validity of the SAQ Score among experts.
b. To assess the construct validity of the SAQ Score among patients with hypertension in primary care settings.

Study 2: To assess the face and content validity of the Perceived Self-efficacy of Sodium Counselling (PSSC) scale to assess physician self-efficacy in providing dietary sodium advice with their patients.

Study 3: Primary Objective: To determine the feasibility of a pilot randomized controlled trial (RCT) protocol to evaluate the impact of the Sodium Calculator (SC) as an eHealth intervention to improve physician-delivered dietary advice on sodium reduction in patients with hypertension in primary care.

a. To assess the process, resource, management and scientific feasibility of the developed pilot RCT protocol according to Thabane's (2010) criteria
b. To descriptively examine the preliminary efficacy of the SC in:
    i. Quality of sodium reduction advice given by physicians in the Control Group and Experimental Groups.
    ii. Physician self-efficacy when providing sodium reduction advice to their patients with hypertension.

CHAPTER 4.0: DEVELOPMENT AND VALIDATION OF THE SODIUM ADVICE QUALITY SCORE

Student's Contributions

The original idea for this study and its design were developed in collaboration with my supervisor JoAnne Arcand, who also provided guidance and expertise in all subsequent components of this study. I conducted the literature search to identify validated measurement tools for our study outcomes and developed the first draft of the Sodium Advice Quality (SAQ) Score, as well as other study materials (eg: demographic questionnaire). I developed the study protocols for both stages of validation. For stage 1 of the validation (face and content validity) I assisted in the oversight and direction of the development of the feedback questionnaire to collect expert feedback, recruitment and data analysis by our undergraduate practicum student. I reviewed expert feedback on the tools, compiled into themes and then compared them to the themes organized by our undergraduate student, Amber Armstrong-Izzard, for consistency. I made edits to the SAQ Score based on both rounds of expert feedback. For Stage 2 (validation of construct validity) I collected data from patients with hypertension in a primary care clinic, developed the study database and designed the analysis of the data with the help of JoAnne Arcand. I carried out the analyses independently. I then completed the original interpretation of the data and prepared an abstract for submission to the American Society of Nutrition. A manuscript is in preparation.

Presentations and Publications:

This abstract (validation of construct validity) was accepted to the American Society of Nutrition (ASN) Conference in Baltimore, Maryland June 8-11, 2019. Titled: Assessment of Construct Validity of a Tool to Measure the Quality of Brief Advice for Dietary Sodium Reduction by Healthcare Providers (Jefferson, Armstrong-Izzard & Arcand, 2019).

Study 1 Abstract

Objective: To develop and validate a tool to measure quality of brief advice about sodium by healthcare providers.

Methods: Development and validation of the Sodium Advice Quality (SAQ) Score was carried out in 4 steps: i) A literature search, ii) tool development using standard procedures in instrument design, iii) assessment of face and content validity among experts, and iv) assessment of construct validity among patients with hypertension.

Results: *Development, and face and content validity*: The initial iteration of the 8-question survey was developed using evidence-based best practice principles for sodium reduction. Feedback from 14 experts resulted in the addition of 2 questions and 4 sub-questions and modifications to question language and structure. There was high agreement among experts that the SAQ Score had face and content validity. *Construct validity*: Forty patients were randomized to complete the Sodium Calculator (SC) and received either high-quality or low-quality sodium reduction advice by a registered dietitian. Participants completed the revised SAQ Score based on this interaction, which was scored and compared to expected scores of 5 and 16 based on the intervention. The mean SAQ score was 6.8 ± 3.4 in the low-quality advice group and 14.8 ± 1.3 in the high-quality advice group. The high-quality advice scores observed were statistically similar to the expected score of 16 ($p<0.001$), but the low-quality advice scores were not. Overall, the low-quality advice score was significantly lower than the high-quality advice score ($p<0.001$).

Conclusions and Implications: The SAQ Score showed evidence of being a valid tool to measure the quality of brief sodium reduction advice provided by healthcare providers, and is deemed an appropriate tool to measure this outcome in future research.

4.1 Introduction

Hypertension, the leading cause for death worldwide, is a risk factor for cardiovascular and cerebrovascular disease morbidity and mortality (Aburto et al., 2013; Alam et al., 2019; Bromfield & Muntner, 2013; Hornsten et al., 2016). Hypertension affects 22.6% of Canadian adults, which is roughly 8 million Canadians (Padwal et al., 2016). Sodium intakes over the Chronic Disease Risk Reduction (CDRR) level of 2300 mg have a causal, linear relationship with high blood pressure and hypertension incidence in studies of rigorous methodological quality (The National Academies of Science Engineering and Medicine, 2019). Despite the well evidenced connection between high sodium intakes and hypertension, Canadians continue to consume an estimated 2760 mg/day, 20% above the CDRR level (Health Canada, 2018), and 38% above the 2000 mg/day sodium recommendation for individuals with hypertension (Nerenberg et al., 2018). All age and gender groups currently exceed the CDRR level (Health Canada, 2018; Nerenberg et al., 2018). Reducing dietary sodium intake is evidenced to improve blood pressure, and therefore reduce risk of cardiovascular disease; as such global public health efforts have been implemented to reduce sodium intakes.

For sodium reduction to be effective, action at both the population and individual level is critical. Healthcare providers, including registered dietitians and physicians, are key agents of change in promoting health behaviour change among patients. This is relevant since the majority of chronic disease management occurs in primary care settings, with 77% of Canadians visiting their physician annually (Nabalamba & Millar, 2007). The importance of this patient-physician interaction was highlighted in a number of studies demonstrating that patients who are not asked to reduce their sodium intake by

their healthcare provider are less likely to do so (Arcand et al., 2013). This suggests that efforts aimed at improving the quality and implementation of dietary advice in clinical settings may improve individuals' action in reducing dietary sodium.

Primary care physicians are in an opportunistic role to provide advice and health behaviour counselling, which is known to have small but effective outcomes on health markers including cholesterol, body weight, blood sugar, and blood pressure (Elliott & Cifu, 2015; Hardcastle et al., 2008; Lin et al., 2014a; Patnode et al., 2017; Pool et al., 2014; Rose et al., 2013). However, implementation of nutrition guidelines and diet related advice are generally provided at a suboptimal rate (Cabana et al., 1999; Quader et al., 2017; Wynn et al., 2010). Quality of care, the extent to which healthcare provider care is consistent with up to date evidenced-based practice guidelines, is vital to improve clinical outcomes for patients (Hanefeld et al., 2017; Hrisos et al., 2009). However, there are no known ways to assess the quality of nutrition care provided in brief encounters in clinical settings. Previous studies that have examined quality of care have used extraction of data from patient health insurance claims, health provider reports, from medical charts, or from patients themselves as data collection methods (Bertsimas, Czerwinski, & Kane, 2013; Hrisos et al., 2009). However, there are limitations to some of these data collection methods: physician reports tend to overestimate the quality of care, while chart reviews are shown to underestimate (Luck, Peabody, Dresselhaus, Lee, & Glassman, 2000; Stange et al., 1998). Furthermore, direct measures are intrusive, can introduce bias by promoting socially desirable behaviour, are time consuming, costly, and are not realistic for larger studies (Hrisos et al., 2009). Patient report of the patient-physician interaction correlates with direct observations of physician behaviour, and patients have been found

to successfully be able to recall receiving the intervention (Pbert et al., 1999; Sciamanna, Goldstein, Marcus, Lawrence, & Pinto, 2004). Therefore, it is deemed an appropriate means of measuring quality of care. Additionally, patient-reported outcomes are a way to collect information from the patient's perspective, which is important to gather an understanding of whether healthcare services improve patient care (Canadian Institute for Health Information, 2014).

There are validated patient-reported tools to measure quality of care, specifically advice, in the literature, however they are designed to assess physician-delivered interventions in smoking cessation, weight loss, dietary fat reduction, alcohol modification, and physical activity rather than sodium (Adams, Ockene, Wheller, & Hurley, 1998; Hogan, Adams, Wahid, & Wilson, 2005; Ockene, Adams, Hurley, Wheeler, & Hebert, 1999; Ockene et al., 1991; Pbert et al., 1999; Sciamanna et al., 2004). A number of these studies utilized the patient exit interview, a tool developed to evaluate the patient's perception of counselling by using a score to determine quantity (overall score) and quality (identifying specific intervention steps provided by physician) (Ockene et al., 1991). Only one tool, the Behaviour Change Counseling Index (BECCI), completed using direct observation, has been created to evaluate the quality of in-depth motivational interviewing and counselling for dietary behaviour change (Lane et al., 2005). Importantly, this tool does not support the evaluation of brief nutrition counselling and advice, which presumably makes up the majority of healthcare provider-patient interactions related to dietary behaviours. To address this gap, a Sodium Advice Quality (SAQ) Score was developed to capture healthcare provider advice related to the type of sodium reduction advice provided, the frequency of that advice and estimated duration of

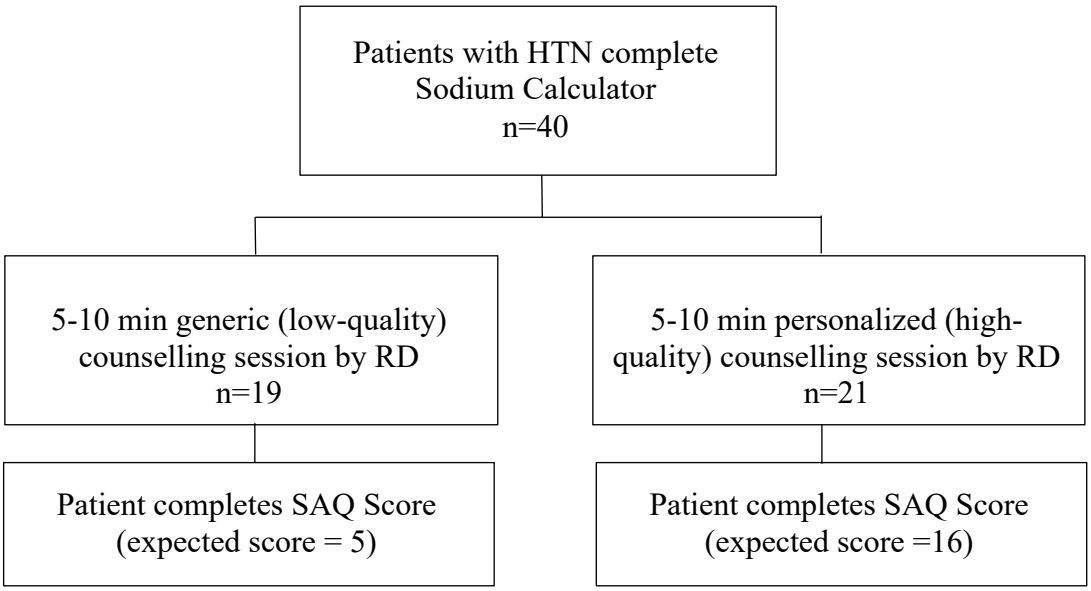
the discussion related to dietary sodium. A validated tool to measure provision of dietary sodium advice by healthcare providers can help to assess quality of care provided to patients and direct the development of interventions aimed at healthcare providers to improve quality of care. The overall objective of the current study was to assess the face, content and construct validity of the SAQ Score. Specifically, this outcome measure tool is needed for a feasibility study (Study 3 of this thesis), as well as a phase 3 randomized controlled trial to determine the efficacy of the SC in its ability to assist physicians in providing better quality sodium reduction advice.

4.2 Methods

4.2.1 Study design.

In order to produce a valid tool to measure quality of sodium reduction advice, two study designs were developed. **Stage 1** of this study included the development of the SAQ Score, which was based on a literature search of existing tools, expert input, and sodium reduction evidence-based practices. Face and content validity were then assessed among two iterative rounds of expert review and feedback. **Stage 2** assessed the construct validity of the SAQ Score in a randomized study where participants were allocated to receive high-quality or low-quality advice for sodium reduction advice (Figure 2). Ethics approval was obtained by Ontario Tech University (University of Ontario Institute of Technology) Research Ethics Board (#14625). The entirety of the study took place between February 2018 and June 2019.

Figure 2. Stage 2 SAQ Score Validation Study Design



4.2.2 SAQ Score development methodology

SAQ Score development followed standard procedures in instrument design: 1. determining content domain (body of knowledge); 2. sample from content (item generation); 3. instrument construction (Carmines, 1979; Nunnally, 1994). Content domain is typically identified by a literature review of the topic being measured to ensure the survey items are reflective of the research objectives (Bowling, 2014). The SAQ Score was based on content domains demonstrated to facilitate effective exchange of knowledge and advice on sodium reduction.

The structure of questions for the SAQ Score was modelled after the Patient Exit Interviews used by Pbert et al. (1999) and Sciamanna et al. (2004) for a measure of physician counselling in smoking and physical activity contexts, shown in Appendix 1. The patient exit interview for assessing physical activity counselling was validated against video-taped sessions, which found overall agreement between the recorded

sessions and patient responses ($p<0.01$) (Sciamanna et al., 2004). The SAQ Score was developed based on these validated Patient Exit Interview surveys, as well as highly documented best practice principles specifically for sodium reduction. The SAQ Score was designed to be completed immediately following the patient's appointment with their physician to reduce recall bias, taking no more than 3-4 minutes to complete to avoid overburdening participants.

4.2.3 Procedures - Stage 1

Subjects and recruitment. To assess face and content validity, the SAQ Score was provided electronically to experts in medicine, nutrition, cardiovascular disease, hypertension and/or survey development for review. The literature suggests that content validity can be sufficiently assessed with at least five experts; as the number of experts increases the probability of chance agreement decreases (Yaghmaie, 2003). Fourteen experts who possessed the qualifications to accurately assess the content validity of the instruments were sent an email with the objectives and request for participation to provide feedback via online questionnaires.

Study protocol. Informed consent and feedback were collected via an online form between February 2018 to March 2018 from all fourteen experts, yielding a response rate of 100%. The SAQ Score was also sent as a word document so that participants had the option of sending additional feedback as tracked changes. Experts were provided with background information on the rationale of the SAQ Score (i.e. what it aimed to measure), the methodology used to create the tool and the intended application of the tool. There were two iterative rounds of expert feedback. After each round, feedback was

consolidated into themes and the SAQ Score was then modified accordingly, based on these themes. In cases where there was conflicting opinions or feedback provided the research team made a final decision on the inclusion, exclusion or addition of questions and feedback.

Outcome measures. An online tool feedback survey, (Appendix 2), was adapted from an existing survey to measure face and content validity (Simon & White, 2016). It contained 16 questions which were adapted to reflect the components of the SAQ Score. Responses were based on a 5-point Likert scale (E.g.: 1=Strongly Disagree, 3= Neither agree nor disagree, 5= Strongly Agree). Specifically, the validation processes captured expert opinions on usability, missing or irrelevant questions and components, and if they felt the tool could discriminate between high and low-quality advice on sodium reduction. Four open-ended questions for additional narrative responses about the SAQ Score were also included. Finally, participants were asked to comment on grammar, clarity, and any editorial aspects.

Data analysis. Data from the feedback survey are presented as frequencies for the expertise of the experts, and frequencies and proportions for the responses of the 5-point Likert scale questions (Strongly Disagree to Strongly Agree). These were collapsed into 'Agree', 'Neither Agree nor Disagree' and 'Disagree'. Open ended questions were reviewed and organized according to themes of feedback, and the SAQ Score was refined and revised based on these themes. In some cases, these open-ended questions were also reported as frequencies.

4.2.4 Procedures - Stage 2

Subject and recruitment. Patients were eligible to participate in the study if they were >18 years of age with a new or existing diagnosis of hypertension (resting blood pressure of ≥140/80 mmHg), or if they had pre-hypertension (resting blood pressure between 120/80-139/89 mmHg) (Leung et al., 2016; Nerenberg et al., 2018). Their blood pressure could be controlled or uncontrolled, and they could be taking or not taking anti-hypertensive medication. They must have had the ability to clearly see the screen of a tablet or computer and be fluent in English. Patients were excluded if they had a diagnosis of a condition or an event (e.g. car accident) affecting memory.

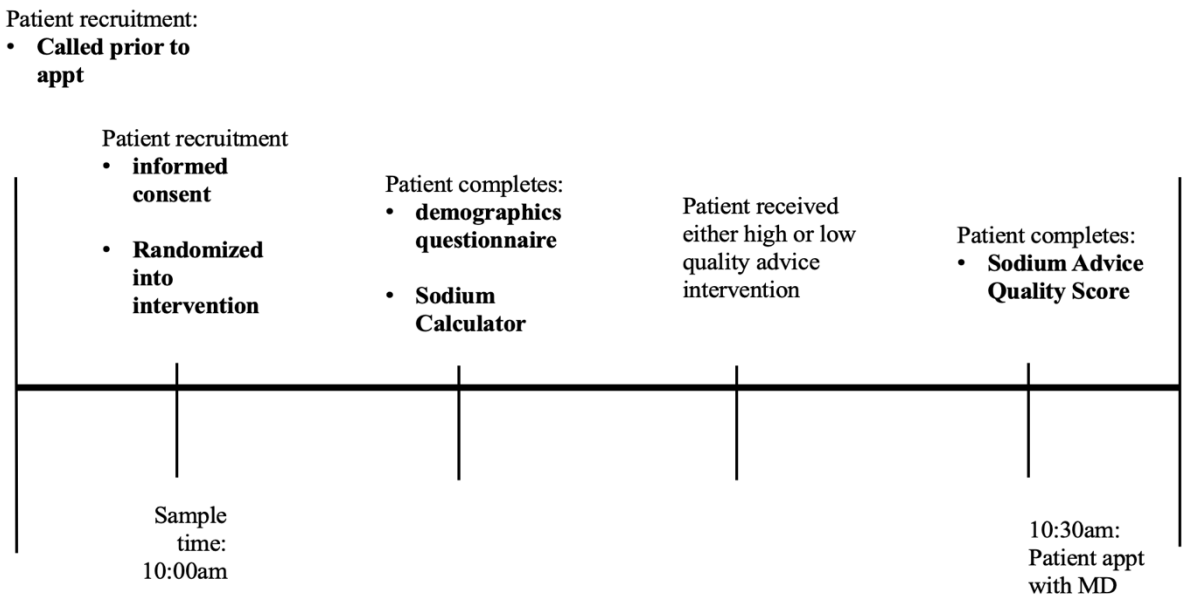
Study procedures. After providing informed consent, patients were randomized to a structured high-quality sodium reduction advice group or low-quality sodium reduction advice group. This was so the SAQ scores in each advice group could be compared to each other to capture differences in quality of advice on sodium reduction. Randomization was completed by having patients select a Manilla folder with a unique study ID labelled on the front. Participants that chose odd study IDs were randomized to the low-quality advice intervention where they were provided with minimal sodium reduction advice. Those that selected even study IDs were randomized to the high-quality advice intervention where they were provided with more detailed, tailored sodium advice. Patients in both groups received their advice from a registered dietitian. Topics discussed corresponded to the domains measured on the SAQ Score, such as estimated sodium intake compared to recommendations for their age and gender; health benefits of a low sodium diet; main contributing sources of sodium in their diet; which foods should be

limited and/or increased; and other tailored strategies to help patients lower their overall sodium intake. Participants were then provided with a generic print handout on sodium reduction. This discussion took ~5 minutes and aimed to result in a perfect SAQ score by covering all domains of the SAQ Score (16/16). Those randomized to the low-quality advice group received minimal intervention, which simply included a comparison of their sodium intake with the recommendations. These participants were provided with the same generic print handouts. The registered dietitian did not discuss specific types of food to limit or strategies to reduce sodium intake. This discussion took <1 minute and aimed to result in a low SAQ score (5/16). A score of 0/16 was not expected as some of the domains on the SAQ Score needed to be addressed.

Once randomized, participants completed a basic demographic questionnaire capturing information such as age, sex, ethnicity, if they had previously received dietary advice from a physician or registered dietitian and their views on diet and sodium and their impact on health. This was followed by completion of the SC to provide an estimate of sodium intake. These questionnaires were all completed on a tablet. The registered dietitian then provided either high or low-quality advice on sodium depending on group allocation. After the advice was provided, the participant was given a paper copy of the SAQ Score, and were instructed to complete based on the interaction with the registered dietitian. Specific emphasis was placed on evaluating the current session with the registered dietitian, on that day only, rather than previous discussions that they have had with healthcare providers. Additionally, participants were asked not to answer the questions based on what sodium reduction strategies they were already doing at home. While patients completed the SAQ Score, the registered dietitian left the room to

minimize reporting bias. Once completed, participants placed the completed SAQ Score back into a Manilla envelope and sealed it so that it would remain confidential (Figure 3).

Figure 3. Stage 2 SAQ Score Validation - Study Procedures



Outcome Measures. The primary outcome of stage 2 was to assess the construct validity of the SAQ Score to determine if it could differentiate between high and low-quality advice for sodium reduction. Each question in the SAQ Score was weighted, equaling a possible total score of 16. The SC was completed by patients to determine their estimated daily sodium intake.

Data Analysis. Descriptive statistics were calculated: frequencies, percentages, means, medians, standard deviations. Between group comparisons of high versus low-quality advice was conducted using the Mann Whitney U test. Expected scores for each group (5

and 16) were compared to their respective groups' median SAQ score using the Wilcoxon Signed Rank Test. Statistical significance was set a $p<0.05$. SPSS Version 25 was the statistical software used (IBM Corporation, 2017).

4.3 Results

4.3.1 SAQ Score development

The first draft of the SAQ Score consisted of 8 questions, with 1 question containing 8 sub-questions on specific sodium reduction strategies. These questions aimed to capture outcomes related to the quality of sodium reduction advice including: frequency of discussion about sodium, if the healthcare professional initiated the conversation, if or what specific recommendations were made, if their advice was framed in a positive or negative frame, and if they provided specific advice/strategies to reduce sodium. Strategies incorporated into the SAQ Score were evidence-based strategies found in the literature based on current clinical practices to reduce dietary sodium intake. These included food label reading, education on choosing fresh rather than packaged goods, avoiding salt containing seasonings, rinsing specific canned goods to remove excess sodium and purchasing low, reduced or non-sodium options (Cobb et al., 2012; Nerenberg et al., 2018). Patient/individual knowledge of these principles has been shown to be effective for reducing dietary sodium intake in one's diet (Cobb et al., 2012). For each question, patients are able to answer 'yes', 'no' or 'not sure', except for question 8 where they were asked to indicate how much time (presented as a range) was spent discussing sodium.

In order to quantify the quality of advice on sodium reduction a weighted point system was developed, with a highest possible score of 13 for the first iteration of the tool. The weighting of each question varied, reflecting the importance of the question.

4.3.2 Stage 1: Face and content validity

Fourteen experts in hypertension, cardiovascular disease or stroke, nutrition and/or sodium, survey development, physicians or medical students, and registered dietitians participated in the study. Twelve experts participated in round 1 (experts 1-12) and two experts participated in round 2 (experts 13-14) (Table 3).

Table 3. Expertise of Experts

	HTN	CVD/Stroke	Nutrition and/or sodium	Survey development	Physician /medical student	PhD	Registered Dietitian
Expert 1	■		■			■	■
Expert 2			■			■	
Expert 3	■		■				
Expert 4					■	■	
Expert 5	■	■	■				■
Expert 6			■				
Expert 7			■				■
Expert 8	■		■	■		■	■
Expert 9			■	■		■	■
Expert 10			■	■			
Expert 11					■		
Expert 12		■					■
Expert 13			■				
Expert 14					■	■	

Expert feedback. In the first round of feedback, all twelve experts (100%) agreed via questionnaire that the questions in the SAQ Score were clear and concise, neutral and unbiased, respectful and appropriate for the target population. Importantly, 100% of experts also believed the SAQ Score was capable of appropriately measuring sodium advice. There were a few agreements that ambiguous questions were present, time to complete may not be appropriate, unsuitable wording for this population and that not all of the questions relevant to assess dietary sodium advice were included (Table 4). Details justifying these responses were summarized in Appendix 3. Based on this feedback 2 questions and four sub-questions were added. Two experts were asked to review this modified version. Feedback in round 2 indicated minor grammatical adjustments and the separation of one question into 2 separate questions to provide better ascertainment of actions (Table 4). An important result of the feedback questionnaire was the overall positive response to whether the tool would be able to discriminate between high-quality sodium advice and low-quality sodium advice. Of the ten responses (10 experts), eight (80%) stated they thought the tool would be able to discriminate and two (20%) indicated that it was likely, but provided their rationale for the reasons why the SAQ Score may not be able to do so. Minimal recommendations were provided, as outlined in Table 5.

Overall, narrative feedback provided fell into four themes: content, question construction, language and typos or errors. Five general comments (41.7% of comments) were made regarding content of the questions, four general comments (33.3% of comments) were made regarding the construction of questions, two comments (16.7% of comments) were made regarding language used and one comment (8.3% of comments) was made regarding a typo.

Table 4. Expert Feedback Questionnaire: Both feedback rounds

	Round 1 (n=12)			Round 2 (n=2)		
n=14	**Disagree n (%)**	**Neither Agree nor Disagree n (%)**	**Agree n (%)**	**Disagree n (%)**	**Neither Agree nor Disagree n (%)**	**Agree n (%)**
The questions appropriately measure information regarding dietary sodium advice	0 (0)	0 (0)	12 (100)	0 (0)	0 (0)	2 (100)
The questions are clear and concise	0 (0)	0 (0)	12 (100)	0 (0)	0 (0)	2 (100)
The questions are asked in a neutral and unbiased tone	0 (0)	0 (0)	12 (100)	0 (0)	0 (0)	2 (100)
The questions asked are respectful and mindful towards patients	0 (0)	0 (0)	12 (100)	0 (0)	0 (0)	2 (100)
The format of the survey is appropriate for patients	0 (0)	0 (0)	12 (100)	0 (0)	0 (0)	2 (100)
The questions are direct and specific	0 (0)	1 (8.3)	11 (91.7)	0 (0)	0 (0)	2 (100)
Patients will understand the questions being asked	0 (0)	1 (8.3)	11 (91.7)	0 (0)	0 (0)	2 (100)
There are no ambiguous questions	1 (8.3)	0 (0)	11 (91.7)	0 (0)	0 (0)	2 (100)
There are no questions that are unnecessarily included. If so, please provide details of what should be removed.	0 (0)	1 (8.3)	11 (91.7)	0 (0)	0 (0)	2 (100)
The questions asked do not lead the participants to a specific response	0 (0)	1 (8.3)	11 (91.7)	0 (0)	0 (0)	2 (100)
There are no double-barreled questions (two questions in one)	1 (8.3)	1 (8.3)	10 (83.4)	1 (50)	0 (0)	1 (50)
The language and terms used are understandable by patients	1 (8.3)	1 (8.3)	10 (83.4)	0 (0)	0 (0)	2 (100)
The weighting scheme accurately ranks each question appropriately	0 (0)	2 (16.7)	10 (83.4)	0 (0)	0 (0)	2 (100)
All of the questions are relevant to assess dietary advice about sodium reduction have been included? If not, please provide details of what we missed. *	2 (20)	0 (0)	8 (80)	0 (0)	0 (0)	2 (100)
The time it takes to complete the survey is appropriate for primary care clinics	1 (8.3)	2 (16.7)	9 (75)	0 (0)	1 (50)	1 (50)
Additional Question asked based on feedback from round 1: Do you think it would be important to ask the patient the specific amount of sodium they were told they should consume in a day (eg: 2300mg, 2000mg, 1 tsp salt) as a sub-question of question # 3?	N/A	N/A	N/A	1 (50)	0 (0)	1 (50)

***n=10**

Table 5. SAQ Score's Perceived Ability to Discriminate Between Quality of Advice

Positive comments supporting that the SAQ Score was capable of discriminating between high quality advice and low quality advice:
'I think that this survey can depict a good picture of the quality of advice given by the physician. The questions that are targeted in this tool are the key points of dietary advice in a salt reduction strategies and therefore very relevant for determining dietary advice quality. In addition, assessment of time spent with the patient discussing this strategies is an important measure to capture and a strength of this tool.' *'Yes, the scoring scheme is adequate. It doesn't give room for ambiguous thresholds therefore, able to assess appropriately.'*
Suggestions to strengthen the possibility that the tool could differentiate the quality of advice:
'Yes. I would suggest being more specific in Question 3 ... Is it possible to specify how much sodium (doctors may say how much, but if its not relevant to that patient it is useless - i.e. 1 tsp/day vs. 2000 mg/day etc).... and more specific with Question 7e) about what to look for on a label... i.e. aiming of 5% or less Daily Value of sodium per day... In my opinion, this will help discriminate between high and low quality advice.'
Comments on potential of the SAQ Score to be able to discriminate quality of advice, but had some potential unknowns:
'I believe the tool can discriminate the level of patient knowledge regarding sodium restriction; whether patients interpret the advice as coming from their physicians correctly is less clear.' *'the critical issue becomes relying on pt feedback lots of work done to show pts retain very little they are told you are asking many questions and not sure reliability/validity of pts feedback might be interesting to ask them to answer this survey at time of exit interview and then contact by phone 3 days later and ask same questions'*

*Appendix 4 demonstrates the final SAQ Score based on feedback received from experts.

4.3.3 Stage 2: Assessment of construct validity

Patient characteristics. Overall, patients (n=41) were 71.1 ± 7.7 years old, 51% male with a mean BMI of 32.2 ± 6.0. Patients had 3.3 ± 1.9 comorbidities and were taking 1.8 ± 1.0 antihypertensive medications with an average blood pressure of 131/70 mmHg. Only 17.5% and 25% of patients had received previous counselling from a registered

dietitian and family doctor, respectively. Patients had a mean daily sodium intake of 2860 ± 1910 mg/day (Table 6). There were no significant differences between groups.

Table 6. Stage 2 SAQ Score Validation - Patient Characteristics

	Overall (n=40)	Low quality sodium reduction advice (n=19)	High quality sodium reduction advice (n=21)	p value
Men (%)	51	53	47	0.901
Age (y)	71.1 ± 7.7	69.4 ± 8.4	72.5 ± 6.7	0.254
# of comorbid conditions	3.3 ± 1.9	2.9 ± 2.1	3.7 ± 1.6	0.142
# of BP medications	1.8 ± 1.0	1.4 ± 0.8	2.1 ± 1.1	0.100
Systolic blood pressure (mmHg)	131 ± 15.3	130 ± 12.9	131 ± 17.4	0.691
Diastolic blood pressure (mmHg)	70 ± 8.4	73 ± 7.8	68 ± 8.5	0.98
BMI (kg/m^2)	32.2 ± 6.0	31.9 ± 6.3	32.5 ± 5.8	0.839
Estimated sodium intake (mg/day)	2860 ± 1910	3023 ± 2201	2705 ± 1639	0.921
Had prior dietary sodium counselling (%)				
By dietitian n (%)	7 (17.5%)	4 (21%)	3 (14%)	0.822
By family doctor n(%)	10 (25%)	3 (16%)	7 (37%)	0.414

Mean ± standard deviation

SAQ scores. The mean SAQ score was 6.8 ± 3.4 (range: 2-14) in the low-quality advice group and 14.8 ± 1.3 (range:10-16) in the high-quality advice group, which were significantly different (p<0.001, Table 7). The high-quality advice scores observed were statistically similar to the expected score of 16 (p<0.001). However, the low-quality advice scores compared to the expected scores for this group did not achieve statistical significance (Table 7). The frequencies of the SAQ scores compared to the expected score for each group were also computed. Overall, the low-quality group SAQ scores were greater than the expected score of 5 for 63% of study participants, with 5% of scores being the same as the expected, whereas the SAQ scores in the high-quality group were more often less than the expected score of 16 (76%), with 24% of scores being the same as the expected score of 16 (Table 7).

Table 7. SAQ Scores

	Low Quality Advice* n=19	**High Quality Advice** n=21**	**P value***
Mean SAQ score	6.8 ± 3.4	14.8 ± 1.3	p<0.001
Median SAQ score	6.0 (2-14)	15.0 (10-16)	
Expected score (ES)	5	16	
P Value (Compared to ES)	p=0.065	p<0.001	
Frequencies of SAQ Scores compared to Expected Score [n (%)]			
Expected score > SAQ score	12 (63%)	16 (76%)	
Expected score < SAQ score	6 (32%)	0 (0%)	
Expected score = SAQ score	1 (5%)	5 (24%)	

* Mann-Whitney U test
+ Wilcoxin Rank Sum test

4.4 Discussion

This study aimed to examine if a newly developed patient exit interview, the SAQ Score, has face, content and construct validity to assess the quality of care provided by healthcare providers in sodium reduction management. Overall, our results show the SAQ Score shows evidence of being a valid tool to measure the frequency and type of sodium reduction advice provided by healthcare providers, a conclusion made based on a high level of agreement among experts. All experts were in agreement that the questions in the SAQ Score were clear and concise, presented in a neutral and unbiased in its tone, respectful and mindful towards patients and appropriate for the target population in both rounds of feedback. Importantly, the majority of experts thought the tool would be able to discriminate between high and low-quality sodium reduction advice. The findings from Stage 2 confirmed this hypothesis. When comparing the mean high-quality advice score to the expected score of 16 it was found to be statistically similar ($p<0.001$), indicating that it has the capability to detect high quality sodium advice. However, the mean low-quality advice score compared to the expected score of 5 was not significant ($p=0.065$), indicating that it is not as capable of detecting low quality advice. This may be due to a small sample size. There was a larger range of scores seen with the low-quality advice group (2-14) than the high-quality advice group (10-16), which may also explain why the mean low-quality score was not found to be statistically similar to the expected score.

The SAQ scores in both the high-quality and low-quality advice groups were slightly different than anticipated. A larger range in SAQ scores were seen compared to what was expected. It is hypothesized that the low scores in the high-quality intervention could be due to patient disinterest in changing dietary behaviour if their SC results were

indicative of appropriate sodium intake, or overall disinterest in changing dietary behaviours. Inclusion criteria were also very broad as participants were only required to have a diagnosis of hypertension. There was no exclusion criteria related to reason for appointment, so patients may have been disinterested in their results if they were preoccupied or anxious with the reason for their upcoming appointment. This may explain lower than expected scores since memory and anxiety levels are connected, which can affect the ability to recall information (Jansen et al., 2008; Kessels, 2003). There is also a linear association between the amount of information provided and the extent of recall, suggesting that those in the high quality advice group that scored lower on the SAQ Score may not have reported everything that was discussed (Safeer & Keenan, 2005).

High scores in the low-quality advice group was not surprising, as overestimation in the quantity of care has been previously seen in the literature with patient exit surveys when assessing physical activity advice (Pbert et al., 1999; Sciamanna et al., 2004). These studies have pointed to the possibility that patients may overestimate the quantity of the intervention provided when asked immediately after appointments, suggesting that patients may recall previous encounters with their physician (Pbert et al., 1999). Possible explanations for these observations might be: patients gave their physician higher scores for quality of advice provided due to concern of prompting negative repercussions (from a low score) for the healthcare provider; the dietary education obtained in previous appointments with their physician contaminated their responses, or social desirability towards study personnel was introduced. However, patient report still remains more reliable than physician report in recalling lifestyle counselling (Stange et al., 1998).

Considerations for implementing the SAQ Score into future research studies based on these possible explanations for the results found indicate the need for study personnel to i) provide clear, explicit directions to the participant to answer the SAQ Score based solely on the verbal discussion they had with their healthcare provider in the appointment that day, and ii) ensure the patient is able to complete the SAQ Score confidentially. This includes maintaining a protocol that supports the participant in completing the SAQ Score without study personnel influencing or biasing their responses to the best of abilities; communicating that their healthcare provider will not be notified of the results of the SAQ Score; and their healthcare provider will not be penalized based on their answers.

There are some limitations and considerations with this study. First, there is a cultural consideration to the application of the SAQ Score. The participants were predominantly English speaking with only 8% of the study population being a visible minority. This is an important consideration in the applicability of the generalization of the tool. For example, sodium intakes in Chinese and Japanese culture tends to come from salt added to cooking and soy sauce compared to the majority of sodium coming from packaged foods in Europe and North America (Brown, Tzoulaki, Candeias, & Elliott, 2009). In practice, counselling for sodium reduction in these ethnicities may look vastly different in the main contributors of sodium. However, the sodium reduction strategies on the SAQ Score are vague enough to be inclusive of many cultural foods or cooking methods. Although the construct validity was not measured in ethnically and culturally diverse populations, the validation of face and content validity among experts with experience providing care to diverse patient populations is suggestive that the SAQ

Score may still be a valid tool when implemented across different ethnic groups. Thus, it is likely that the SAQ Score remains an appropriate, valid tool to assess the quality of advice on sodium reduction for the general Canadian population. Another limitation of the SAQ Score is that the focus is solely on practitioner behaviors without taking into consideration patient behaviors. It has been suggested that leaving out this information fosters a missing piece in physician-patient shared decision making (Elwyn et al., 2012).

In summary, this study shows that the SAQ Score is a patient exit survey that allows for sodium advice to be assessed as an outcome measure in studies evaluating the quality of care, specifically frequency and type of sodium advice provided by healthcare providers. Patient exits interviews are an important data collection approach in health research and have been used previously to gather data on healthcare provider behaviour during consultations (Hrisos et al., 2009; Ostroff, Li, & Shelley, 2014; Pbert et al., 1999; Sciamanna et al., 2004). The development and validation of the SAQ Score has filled a gap in the lack of assessment tools suitable for assessing the quality of care provided to patients who require sodium reduction as part of chronic disease management. With the considerations stated above for the implementation of the SAQ Score, it is deemed to be an appropriate tool in future studies examining quality of dietary counselling in response to interventions aimed at improving the quality of nutrition care provided by healthcare providers.

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CHAPTER 5.0: DEVELOPMENT AND VALIDATION OF THE PERCEIVED SELF-EFFICACY OF SODIUM COUNSELLING (PSSC)

Student's Contributions

The original idea for this study and its design were developed in collaboration with my supervisor JoAnne Arcand, who also provided guidance and expertise in all components of this study. I conducted the literature search for previously validated measurement tools for our study outcomes (self-efficacy) and adapted an appropriate questionnaire found in the literature to measure physician self-efficacy related to providing sodium reduction advice when no appropriate existing tools were found. I then developed the study protocols for face and content validation of this adapted scale, called the Perceived Self-efficacy of Sodium Counselling (PSSC) Scale. This protocol was the same as those developed for chapter 4 of this thesis for validation of the Sodium Advice Quality (SAQ) Score. I assisted in the oversight and direction of the development of the feedback questionnaire to collect expert feedback, recruitment and data analysis by an undergraduate practicum student Amber Armstrong-Izzard. I reviewed expert feedback on the PSSC Scale, compiled into themes and then compared them to our undergraduate student's themes for consistency. I made edits to the PSSC Scale based on both rounds of expert feedback. I also carried out the analyses independently, and again compared my results to those of the undergraduate student for consistency. I wrote the manuscript associated with this work, as presented in this chapter.

Study 2 Abstract

Objective: To develop and validate a scale to measure self-perceived self-efficacy of physicians in providing sodium reduction advice to their patients.

Methods: Development of the Perceived Self-efficacy of Sodium Counselling (PSSC) Scale was carried out in 3 steps: i) A literature search for existing tools, appropriate scope and domains, ii) adaptation of a similar tool to reflect self-efficacy of sodium counselling, and iii) assessment of face and content validity of the scale among experts.

Results: The initial iteration of the 14-question scale was modified from a validated scale for competence in obesity counselling. Feedback from 14 experts resulted in the removal of 3 questions, 1 question added and 8 modifications to question language. There was high agreement among experts that the scale had face and content validity.

Conclusions and Implications: The PSSC Scale shows evidence of being a valid tool to measure physician self-efficacy in providing sodium reduction advice to their patients.

5.1 Introduction

Physicians are in an optimal position for providing care related to health behaviours for chronic diseases, such as the dietary prevention and management of hypertension that is currently affecting 23% of the Canadian population (Padwal et al., 2016). Patients with hypertension are primarily managed in primary care clinics, therefore this setting is a vital target location to promote the implementation of dietary guidelines through physician-delivered dietary advice and support (Clarke & Hauser, 2016; Dysinger, 2013; Melvin et al., 2017; Wolfenden et al., 2016). Indeed, moderate to intensive diet and physical activity related counselling interventions with involved physicians have had small yet effective outcomes on health markers including cholesterol, body weight, blood sugar, blood pressure and dietary behaviours, and is cost effective (<$50,000 USD/DALY) (Ball., Johnson, Desbrow, & Leveritt, 2013; Booth, Prevost, Wright, & Gulliford, 2014; Elliott & Cifu, 2015; Lin et al., 2014a; Pool et al., 2014; Rose et al., 2013). Although time constraints in primary care are often cited as a limiting factor to such patient-physician discussions, such conversations are impactful. It is well supported that physician led-discussions about health behaviours including diet is enough to trigger patient behaviour change (Ball, Leveritt, Cass, & Chaboyer, 2015; Greene, Hibbard, Alvarez, & Overton, 2016; Jackson, Wardle, Johnson, Finer, & Beeken, 2013; Oberg & Frank, 2009). Therefore, even brief discussions or advice about diet should be encouraged (Cobb et al., 2012).

The rate of Canadian physician-delivered nutrition advice is estimated at 19%, which is sub-optimally low compared to the increasing rate of chronic disease (Ma et al., 2004; Wynn et al., 2010). A number of internal and external barriers to physicians

providing dietary advice have been identified in the literature, including length of time in practice, lack of time, lack of compensation, patient characteristics and reason for appointment, and importantly, physician lack of nutrition knowledge and education, and low self-efficacy (Eaton et al., 2002; Kolasa & Rickett, 2010; Ma et al., 2004; Quader et al., 2017; Wynn et al., 2010).

Self-efficacy is a strong predictor of behaviour, performance and clinical competence, and mediates the relationship between knowledge and action (Bandura, 1977; Mogre et al., 2017; Opacic, 2003). A lack of physician self-efficacy is associated with poor adherence to clinical practice guidelines, including poor rates of counselling about health behaviours for chronic disease management (Bandura & National Inst of Mental Health, 1986; Cabana et al., 1999; Thompson, Schwankovsky, & Pitts, 1993). Low levels of self-efficacy often occur as a result of poor training or knowledge in a particular area, which has been demonstrated with the provision of specific nutrition advice (Al-Muammar, 2012; Cabana et al., 1999; Chiriboga et al., 2003; Kolasa & Rickett, 2010; Kushner, 1995; Lugtenberg et al., 2011; Perrin et al., 2008; Wynn et al., 2010). Thus, improving physician self-efficacy is an important factor as physicians who have higher self-efficacy are more effective in their counselling and are more likely to provide advice on health behaviours (Thompson et al., 1993). Therefore, they are more likely to promote the implementation of clinical practice guidelines (Cabana et al., 1999).

Self-efficacy is an individual's personal belief in their ability to perform a certain task, therefore it is a challenging outcome to rigorously measure, and is typically measured using self-reported surveys (Bandura, 2006; Scherbaum & Cohen-Charash, 2006). It is important to measure and confirm physician self-efficacy in providing sodium

reduction advice in order to facilitate strategies and physician focused interventions that support provision of dietary counselling, as interventions that have improved healthcare provider self-efficacy are positively associated with increased delivery of healthcare services (Cloutier et al., 2018). There are currently only a few tools available for researchers to assess healthcare provider self-reported self-efficacy and competence. Importantly, many of these tools have not been validated and are not specific to the provision of dietary sodium advice specifically in the management of hypertension (Ball & Leveritt, 2015; Burton, Brezausek, Hendricks, Agne, Hankins & Cherrington, 2015; Mihalynuk, Scott, & Coombs, 2003). Such tools to assess self-efficacy must be tailored to the particular domain of interest, as self-efficacy is situation specific (Bandura, 1997, 2006). Therefore, to address this gap, the aim of this study was to develop and validate a questionnaire to measure physician perceived self-efficacy in providing advice related to dietary sodium to patients in primary care. The availability of a valid tool to assess physician self-efficacy is needed as a part of a larger effort to develop an effective intervention to assist physicians in facilitating dietary sodium counselling.

5.2 Methods

5.2.1 Development of the Perceived Self-efficacy of Sodium Counselling (PSSC) Scale methodology.

The questionnaire development involved a review of the literature and expert review. First, a search of the literature was conducted to determine if a measurement tool to assess physician's self-perceived self-efficacy in dietary sodium counselling or any other health behaviours existed. Pubmed, Google Scholar and Scholars Portal were the bibliographic databases searched.

This search resulted in the knowledge that no tool was in existence that measured physician self-efficacy of sodium reduction counselling. However, work conducted by Burton et al. (2015) on the development of a tool to assess physician perceived competence for obesity counselling in chronic disease management was discovered: the Perceived Competence for Obesity Counseling (PCOC) scale. This measurement tool consists of 20 questions, developed based on constructs of the 5A's counseling framework: Assessing risk and motivation to change; Advising lifestyle change; Agreeing with the patient on collaboratively set goals; Assisting in addressing barriers and resources; and Arranging for follow-up, review of the literature and expert opinion (Burton et al., 2015).

This scale was validated among a sample of medical residents and found to significantly correlate to the resident's overall confidence in obesity counselling ($r = 0.60$, $p < 0.01$) (Burton et al., 2015). It has been used in recent obesity counselling research as an outcome measure (Burton et al., 2016). Therefore, to measure physician self-efficacy in sodium reduction counselling, adaptations of the Perceived Competence of Obesity Counselling scale was modelled to reflect physician perceived competence specific to dietary sodium counselling. This adaption of the scale was called the Perceived Self-efficacy of Sodium Counselling (PSSC) Scale. The PSSC Scale was designed to be completed by physicians, taking no more than 2 minutes to complete.

5.2.2 Procedures.

Subjects and recruitment. To assess face and content validity, the PSSC Scale was provided electronically to experts in medicine, nutrition, hypertension, cardiovascular

disease and/or survey development for review, as described in Chapter 4. Fourteen experts possessing these qualifications to appropriately assess the content validity of the PSSC Scale were sent an email with the objectives of the study and a request for participation in providing feedback via online questionnaires. This study was approved by Ontario Tech University (University of Ontario Institute of Technology) Research Ethics Board [#14625] and took place from February 2018 to May 2018.

Study protocol. Experts provided informed consent and feedback using an online survey between February 2018 to March 2018. The PSSC Scale was also sent as a word document so that participants could send additional, detailed feedback as tracked changes. The background of the scale and its development was provided so experts had a rationale for the need of the tool and the intended application. There were two iterative rounds of expert feedback. After each round, feedback was consolidated into themes. The PSSC Scale was then modified appropriately, based on these emerging themes. Where there was conflicting opinions or feedback from experts, the research team made a final decision on the inclusion, exclusion or addition of questions or feedback.

Outcome measures. A survey was adapted from White and Simon (2016) to measure face and content validity (Appendix 5). This online questionnaire, contained 17 questions, adapted to reflect the components of the PSSC Scale. Responses were based on a 5-point Likert scale (i.e.: 1=Strongly Disagree, 3= Neither agree nor disagree, 5= Strongly Agree). The validation processes captured expert opinions on usability, missing or irrelevant questions and content. Three open-ended questions for additional narrative

responses regarding if any questions should be added, removed and overall comments or suggestions for the PSSC Scale were also included. Participants were given the opportunity to edit the PSSC Scale for grammar, wording, clarity, and editorial aspects.

Data analysis. Data are presented as frequencies and proportions for the responses related to the 5-point Likert scale questions (Strongly Disagree to Strongly Agree). Response data were collapsed into categories: 'Strongly Agree' and 'Agree' into 'Agree', and 'Strongly Disagree' and 'Disagree' into 'Disagree'. Open ended questions were reviewed and organized according to themes of feedback, and the PSSC Scale was refined and revised based on these themes.

5.3 Results

5.3.1 Questionnaire adaption and revision.

The PSSC Scale was adapted from the Perceived Competence of Obesity Counselling (PCOC) scale (Burton et al., 2015) and originally consisted of 14 questions related to appropriate content for sodium counselling. Each question in the PSSC Scale can be answered based on a 6-item Likert scale from 'Not at all confident' to 'Very Confident', with the option to select 'Not applicable'. It was developed to take no more than 2-3 minutes to complete. The PSSC Scale captures physician self-reported self-efficacy in providing sodium reduction advice (Figure 4).

Figure 4. PSSC Scale

1. I can personalize sodium reduction advice for each patient I see

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

2. I can collaborate with my patients and formulate a dietary plan for sodium reduction

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

3. I can determine a patient's readiness to change their behaviour to reduce dietary sodium intake

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

4. I can assist a patient with dietary sodium reduction during a brief counseling session

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

5. I can address resistance to change when advising a patient on sodium reduction

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

6. I can work with my patient to select specific strategies to reduce sodium

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

7. I can help patients identify and strategize to overcome barriers to dietary sodium reduction

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

8. I can assess a patient's estimated sodium intake

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

9. I can advise a patient about the health impacts of a low sodium diet

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

10. I can inform the patient about the benefits of sodium reduction on their health

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

11. I feel comfortable referring my patient to a dietitian to provide further support

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

12. I can work with a patient's family/partner to emphasize the importance of dietary sodium reduction

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

5.3.2 Face and content validity.

Fourteen experts in hypertension, cardiovascular disease or stroke, nutrition and/or sodium, survey development, physicians or medical students, and registered dietitians participated in the study. Twelve experts participated in round 1 (experts 1-12) and two experts participated in round 2 (experts 13-14) (Table 8).

Table 8. Expertise of Experts

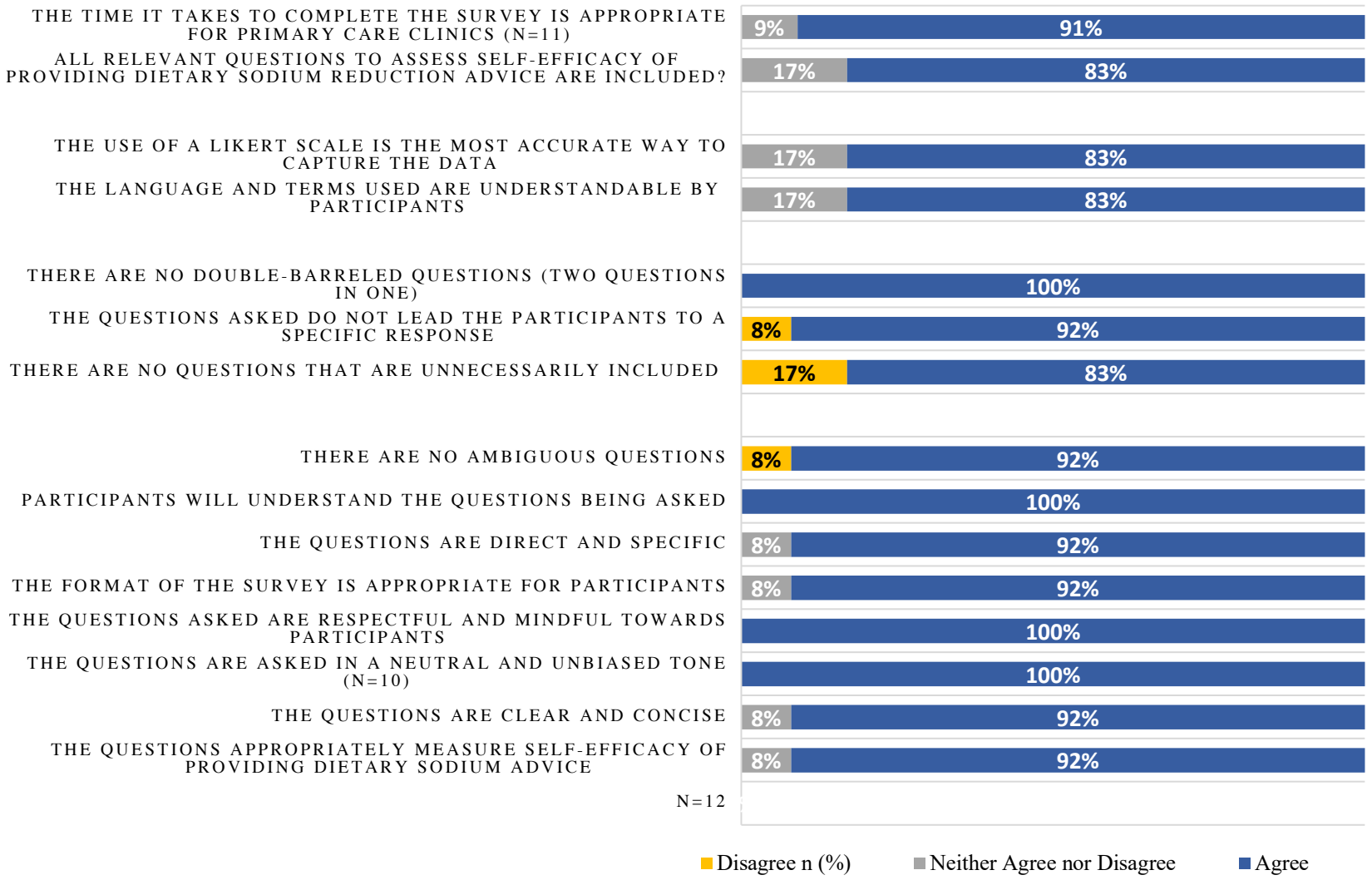
	HTN	CVD/Stroke	Nutrition and/or sodium	Survey development	Primary care physician /medical student	PhD	Registered Dietitian
Expert 1	■		■			■	■
Expert 2			■			■	
Expert 3	■		■				
Expert 4					■	■	
Expert 5	■	■	■				■
Expert 6			■				
Expert 7			■				■
Expert 8	■		■	■		■	■
Expert 9			■	■		■	■
Expert 10			■	■			
Expert 11					■		
Expert 12		■					■
Expert 13			■				
Expert 14					■	■	

All experts (100%) agreed that the questions in the PSSC Scale were neutral and unbiased in its tone, respectful and mindful towards physicians, that participants would understand the questions being asked, and there were no double-barrelled questions. There was only one expert (8.3%) who disagreed that the first draft of the PSSC Scale had no ambiguous questions and did not lead the participants to a specific response. Two experts (16.7%) believed that there were three questions that were added that were not necessary. More specific detail on these questions was provided in open ended comments. Most experts (83.3%) believed that the use of a Likert scale was the best way to capture the information on the domains of interest (Figure 5).

The research team made modifications as a result of the feedback obtained, which included grammatical changes and clarifications among eight questions, as well as the addition of one question and removal of three questions. The final tool had twelve

questions (Figure 4; Appendix 6). Overall, feedback provided fell into one theme: content. No changes were made to the tool after round 2 as reviewers were in agreement.

Figure 5. Expert Feedback Questionnaire on PSSC Scale: Round 1



5.4 Discussion

In this study a 12-question scale, the Perceived Self-efficacy of Sodium Counselling (PSSC) Scale, was developed to measure self-perceived self-efficacy among physicians providing sodium reduction counselling to patients with hypertension. The aim of the study was to determine if the PSSC Scale has face and content validity to measure physician self-efficacy. Overall, it was deemed that the PSSC Scale showed evidence of being a valid tool to measure the self-perceived self-efficacy of physicians on providing sodium reduction advice; this was based on a high level of quantitative agreement among experts. All experts found the PSSC Scale to ask clear, concise and unbiased questions that were not viewed as leading to the user in order to collect participant responses relevant to the objective of the measurement tool.

Physicians play a critical role in promoting the adoption of health behaviours, and self-efficacy plays an important role in physician implementation of clinical practice guidelines such as Hypertension Canada's guidelines for hypertension (Nerenberg et al., 2018). However, to date, there was no way to measure physician self-efficacy related to the provision of dietary sodium advice, the principal dietary recommendations for hypertension and other chronic diseases like heart failure and chronic kidney disease. The PSSC Scale can be used as a measurement tool to evaluate interventions developed to increase physician self-efficacy in implementing guideline recommendations for sodium reduction counselling. The PSSC Scale can also be used in cross-sectional studies to determine what areas providers need tools and education to increase levels of self-efficacy. Self-reported self-efficacy of healthcare providers has been supported in the literature to be an outcome measure as valid as direct observation and patient assessment,

with no statistically significant findings between the methods of assessment (Ammentorp et al., 2013; Axboe, Christensen, Kofoed, & Ammentorp, 2016). However, it is important to note that other literature did not reach the same conclusion unless the domains of investigation are clearly specified (Davis et al., 2006). Response bias can be minimized by a carefully designed protocol and through the method of administration: for example, providing participants the opportunity to complete the scale in privacy and anonymously may decrease social evaluative concerns (Bandura, 2006).

High perceived self-efficacy for counselling in primary care settings has been found to be positively associated with guideline adherent care, increased rates of lifestyle counselling and more time spent on counselling, overall increasing counselling performance, and therefore arguably increased quality of care related to chronic disease management (Bandura & National Inst of Mental Health, 1986; Cabana et al., 1999; Cloutier et al., 2018; Thompson et al., 1993). It is theorized that the provision of counselling, or health education, is based on a number of factors modelled off of Bandura's social cognitive theory, for which self-efficacy is one domain (Bandura, 1977). Factors include quantity and quality of experience, unfamiliar experiences, client trust, self-concept, professional knowledge and skill and vicarious experiences (experiences of colleagues) (Zamani-Alavijeh, Araban, Harandy, Bastami, & Almasian, 2019). This scale is also not able to determine what factors, and to which extent, have impacted the healthcare providers self-efficacy for sodium reduction counselling specifically. It is also important to put into context the self-efficacy score compared to these factors, such as amount of nutrition education and training, length of time in practice etc. as this has been

found to be associated with self-efficacy scores among physicians (Dandavino, Young, Gosselin, Snell, & Bhanji, 2013).

There are some limitations to this study. The PSSC Scale was designed so that it may be utilized to measure changes in response to an intervention; however, construct validity was not assessed in this study. Yet, face and content validity were assessed, which are critical features in ascertaining outcomes from questionnaires. Also, the PSSC Scale was adapted from a previously validated and successfully piloted scale (PCOC) (Burton et al., 2015), with adjustments reflecting the domain of interest (sodium counselling), rather than obesity counselling. Finally, only two experts' feedback, in addition to the research team, concluded that the PSSC Scale was valid for content validity, following modifications from the first round of feedback. However, the literature supports that content validity can be assessed sufficiently with at least five experts, and this study had the expertise of a total of fourteen experts (Yaghmaie, 2003).

In conclusion, the PSSC Scale is a tool with evidence of both face and content validity to measure physician self-reported self-efficacy in sodium counselling. It will be a useful tool for surveillance of physician self-efficacy and potential for measuring the effectiveness of behavioural interventions to improve physician provision of care and adherence to chronic disease sodium guidelines. Specifically, this scale will allow for our future work in the examination of changes to and differences between physician self-efficacy in usual care versus with the support of an eHealth intervention aimed at facilitating dietary sodium reduction advice to patients.

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CHAPTER 6.0: FEASIBILITY OF IMPLEMENTING THE SODIUM CALCULATOR INTERVENTION INTO PRIMARY CARE

Student's Contributions

The original idea for this study and its design were developed in collaboration with my supervisor JoAnne Arcand, who also provided guidance and expertise in all components of this study. I conducted the literature search for similar studies and methodologies to determine gaps in the literature. I then developed the study protocol, data collection materials and put together the REB application. With assistance from community partners and clinic staff, I was responsible for recruiting physicians, modifying study protocols to fit within each unique clinic and corresponding with clinic staff who were assisting with patient recruitment. I met with physicians 1:1 where I instructed them on study protocols, and also conducted a group information session for physicians. Along with assistance from various research assistants (RAs), I was responsible for data collection from patients, physicians and direct observations. The majority of data entry was completed by myself and these RAs, with an additional RA who assisted with validation of data entry. Dr. Arcand, myself and the physician research champion, Dr. Michael Ward, discussed protocol issues, possible solutions and feasibility. With assistance from Dr. Arcand, I developed the plan for data analysis and independently conducted the analyses. I then interpreted and reported on the results of this study.

Study 3 Abstract

Objectives: Determine the feasibility of a protocol designed to examine the impact of the Sodium Calculator (SC) on quality of dietary advice for sodium reduction provided by physicians in primary care settings. The secondary objective was to briefly examine the implementation and preliminary findings of outcome measurement tools developed for the randomized controlled trial (RCT) protocol outcomes (advice and self-efficacy).

Methods: Data to assess feasibility was taken throughout the study timeline based mainly on direct observations by study personnel, and discussions with patients, physicians and clinic staff. Exploratory outcomes were collected through previously developed and validated measurement tools; the Sodium Advice Quality (SAQ) Score, Perceived Self-Efficacy of Sodium Counselling (PSSC) Scale and a SC acceptability scale. Data was categorized into the key aspects of assessing feasibility: process, resource, management and scientific feasibility by Thabane (2010). Assessment of feasibility was determined using Thabane's criteria to evaluate the success of this multi-centre parallel RCT pilot study.

Results: There were several areas of successful implementation of the pilot RCT protocol identified, including: no disruption to physician workflow in four clinics, and no concerns from physicians regarding implementation of the SC intervention itself. Yet, there were also challenges: recruitment, adherence to protocol and resource use. Due to the number and magnitude of modifications made throughout the study, the original protocol was not deemed feasible. However, with the adjustments made throughout the study timeline, it is recommended that if this study is to be implemented as a large scale RCT it should be continued with current methodologies, but some additional modifications are required.

Conclusions and Implications: With modifications, this study protocol will help determine if the SC is a tool that can be used as an intervention to aide physicians in improving their quality of care for their patients who require sodium reduction.

6.1 Introduction

Non-communicable diseases, or chronic diseases, are the leading cause of death globally as presented by the recent Global Burden of Disease study. In this study, sodium was ranked as one of the greatest dietary risk factors (Collaborators, 2019). Sodium intake exceeding 2,000 mg/day, the maximum intake recommended by the World Health Organization (WHO), is a causal risk factor for high blood pressure and increases risk for hypertension, cardiovascular diseases and stroke (Aburto et al., 2013; He et al., 2013; Mozaffarian et al., 2014; Nerenberg et al., 2018; World Health Organization, 2012). In 2017, 3 million deaths worldwide were attributed to high sodium intakes (Collaborators, 2019).

Population level sodium reduction strategies have been implemented globally, and in Canada in 2010. These approaches typically focus on food reformulation, nutrition labelling policies and education (Trieu et al., 2016). However, in Canada, such policies and programs have not resulted in a decrease in Canadians sodium intakes to meet the Chronic Disease Risk Reduction level for sodium of 2300 mg/day (Arcand et al., 2016; Canada, 2018; National Academies of Sciences, 2019), likely because of the voluntary nature of Canadian policies. Consequently, action is also needed on the individual level for sodium reduction to be successful. The WHO (2016) emphasizes the role of primary care in promoting and engaging individuals in behavioural counselling, including diet, to address chronic disease. Nutrition counselling interventions that are feasible and effective are warranted in primary care settings to assist individuals in minimizing health risks (Curry & McNellis, 2015). Interventions aimed at reducing sodium are often considered burdensome by healthcare providers who face numerous barriers to implementation such

as a lack of time, limited knowledge about sodium and nutrition, and low self-efficacy (Lin. et al., 2013; Wynn et al., 2010). However, facilitators to providing dietary counselling are the ability to refer to registered dietitians, increased nutrition education in medical school, compensation for providing dietary counselling, an electronic medical record (EMR) prompting to discuss diet with patients, and a specific app or EMR tool to assist in educating patients about diet (Dash et al., 2019, unpublished). Electronic health (eHealth) tools are emerging as a new way of healthcare delivery and they show promise in improving access to care, improving patient centered care by increasing shared decision making and improved communication, improving the efficiency of chronic disease management, and overall quality of care by improved diagnoses, adherence to clinical guidelines and access to relevant health information (George et al., 2009; Hao et al., 2015; Hunting et al., 2015; Kreps & Neuhauser, 2010; Marzegalli et al., 2008; Palmier-Claus et al., 2013; Praveen et al., 2014; Solomon, 2008; Steele Gray, Khan, et al., 2016). However, at this time there is no eHealth tool that has been routinely implemented into clinical settings to assist healthcare providers in dietary management of their patients requiring dietary sodium reduction.

The Sodium Calculator (SC) (www.projectbiglife.ca) (Appendix 7), is an evidence-based eHealth tool developed to assist individuals rapidly screen and monitor dietary sodium (Arcand et al., 2014). The SC was developed in a Canadian context, considering the sources of sodium and their sodium content, as well as portion sizes consumed. This data was collected from the Canadian Community Health Survey as well as an up to date Canadian food database (Canada, 2018; Fischer et al., 2009a; Schermel, Emrich, Arcand, Wong, & L'Abbe, 2013). The SC has recently been validated against

food records ($r=0.60$, $p<0.001$, Arcand et al., unpublished) as a brief sodium assessment tool, and has also shown the ability to improve user sodium knowledge, attitudes and intended sodium reduction behaviours (Jefferson et al., 2019). Although the evidence to support that the SC shows potential to improve sodium intakes on the individual level, based on its features it is also plausible that it may support healthcare providers in the monitoring of their patients' sodium intake, and act as a clinical decision support tool for providing dietary sodium reduction advice. Whether or not the SC can support the quality of dietary advice provided by physicians and other healthcare providers, especially those in the busy primary care setting, has not yet been tested.

Importantly, behavioural interventions designed for implementation into primary care setting have their own unique barriers. This supports the need to incrementally and iteratively develop and implement these interventions into this practice setting (Burke & Gitlin, 2012; Gitlin, 2013). It is recommended to complete pilot studies (a miniature version of the main trial to test study design and processes) and assess feasibility (determining if the study can be done) as a part of intervention development, evaluation and implementation (Arain, Campbell, Cooper, & Lancaster, 2010). This is to maximize the likelihood of developing a randomized controlled trial (RCT) with both high internal and external validity (scientific robustness and generalizability to real-world contexts) (Arain et al., 2010; Craig et al., 2013). The overall goal of this exploratory stage of research was to conduct a formative study to prepare for a full scale RCT to evaluate the impact of the SC as an eHealth intervention to improve physician-delivered dietary advice on sodium reduction among patients with hypertension in primary care. Therefore, the primary objective of this pilot study was to determine the feasibility of this RCT

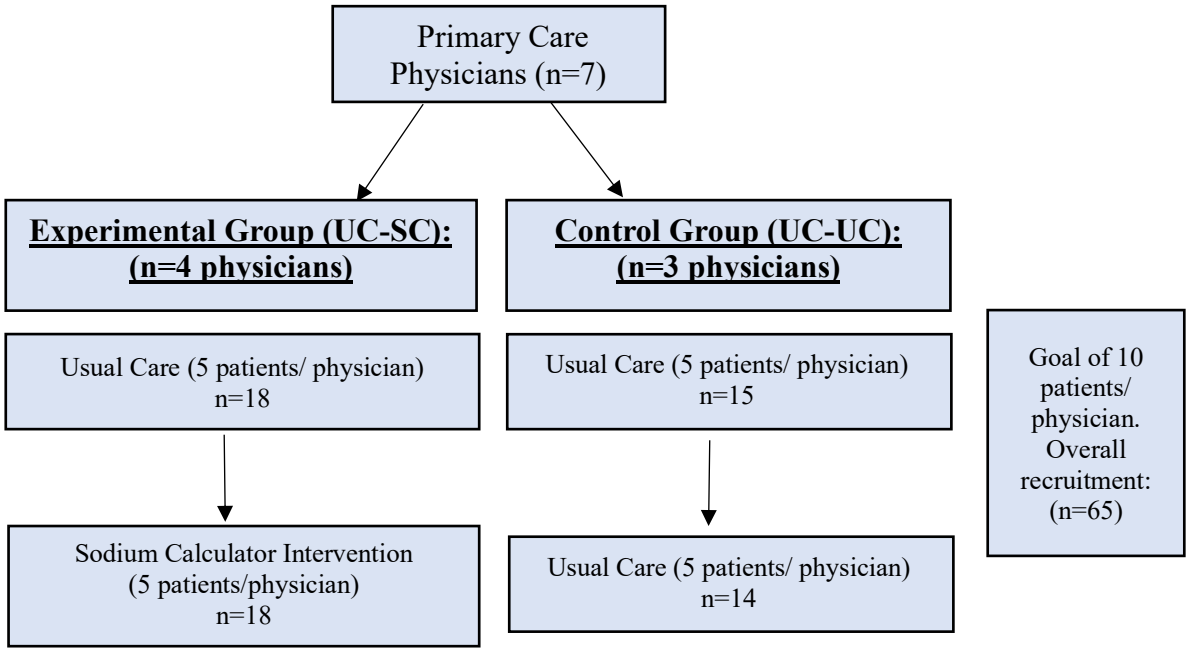
protocol developed to evaluate the effectiveness of the SC intervention. Additionally, the secondary objective of this study included the descriptive preliminary evaluation of the SC intervention on exploratory outcomes; including quality of advice provided by physicians on sodium reduction and physician self-efficacy in providing this advice. These were captured using developed and validated outcome measurement tools: the Sodium Advice Quality (SAQ) Score and Perceived Self-efficacy of Sodium Counselling (PSSC) Scale.

6.2 Study Methodology

6.2.1 Feasibility study methodology – Study design.

This was a pilot study of a multi-clinic, parallel RCT conducted to determine overall feasibility of study protocol and implementation, and a preliminary examination of efficacy of the SC on the exploratory outcomes listed in the objectives. Primary care physicians, the primary participants, were recruited and randomized to either the Experimental Group (UC-SC), or Control Group (UC-UC), where they each provided care for ten unique patients. Randomization was not stratified. The allocation ratio was designed to be 1:1. Patients with hypertension, the secondary participants, were recruited consecutively based on scheduled appointments and were not randomized (Figure 6). This study was approved by the Ontario Tech University (University of Ontario Institute of Technology) Research Ethics Board [#14625] and took place from May 2018 to June 2019.

Figure 6. Pilot RCT Study Design



6.1.2 Subjects and recruitment.

Primary participants: Physicians. Physicians were recruited from four primary care centres in Durham Region. Eligible participants were primary care physicians who provided care to patients with hypertension and were fluent in English.

Physician recruitment. Multiple strategies were applied to recruit physicians. In both strategies described below, a research champion was partnered with to provide direction on how best to reach and engage with physicians. 1) A mass email was sent to physicians in the participating clinics. Interested physicians met with study personnel in one-on-one meetings to obtain the study objectives, detailed protocol and requirements. 2) A lunch information session was also provided at one clinic to recruit physicians. Physicians were

provided with an oral presentation with the same deceptive study objectives, protocol and requirements provided in the one-on-one sessions. Deception of the true study objectives was used in order to blind the physicians to prevent contamination of the data. Physicians were told that the objective of the study was to determine the effectiveness of using the SC as a sodium reduction intervention in primary care to avoid biasing their behaviour.

Randomization procedures. Physicians were randomized into either the intervention or control group at time of consent by selecting a random computer-generated study ID. Odd study IDs were randomized to the Control Group (UC-UC), even study IDs were randomized to the Experimental Group (UC-SC). Physicians were blinded to group allocation until halfway through patient recruitment when it became obvious based on if they were introduced to the SC intervention or not for their remaining five patients. Study personnel were not blinded to physician group allocation due to differences in the sequence of patient study requirements. Patients were not randomized and instead were consecutively recruited for each physician.

Secondary participants: Patients with hypertension. Patients of participating physicians were eligible if they were over 18 years of age with a new or existing diagnosis of hypertension (resting blood pressure of ≥140/90 mmHg) (Collier & Landram, 2012; Leung et al., 2016; Nerenberg et al., 2018). Diagnosis of hypertension could be by both true cuff and patient at home measurements. Their blood pressure could be controlled or uncontrolled, and could be treated with anti-hypertensive medication. These patients were only eligible if they were attending a clinic appointment with their physician that was related to a blood pressure management specific follow-up or an

annual/bi-annual health exam. Based on the nature of the intervention, patients were required to be able to clearly see the screen of a tablet or computer and be fluent in English. Patients who had a diagnosis of dementia or an event affecting memory (e.g. car accident, stroke) were excluded from the study.

Patient recruitment. Initially only one strategy was applied to recruit patients. Eligible patients were consecutively recruited prior to their appointment by clinic staff based on upcoming appointments in the participating physician's schedule. Interested patients were instructed to arrive at their appointment either 15-20 minutes early.

Sample size calculation. A sample size calculation was not conducted for physicians or patients prior to conducting the study since the primary outcome measure of the study was feasibility. Pilot studies are not designed to determine effect size, their purpose is rather to test and refine the study design (Tappin, 2014). The sample size was based on feasibility considerations for the study timeline and total number of physicians in the participating clinics.

6.1.3 Feasibility study protocol.

The assessment of feasibility and implementation for the following pilot RCT protocol was assessed throughout the progression and on completion of the trial. A detailed feasibility methodology is presented in sections 6.1.4-6.1.5 below. The flow of overall study procedures for all participants can be seen in Figure 7.

Physician protocol. After physician enrollment and randomization to a study group, physicians provided care to 10 of their consenting, eligible patients. Physicians were informed which patient appointments to implement the study protocol in through reminders from clinic staff and specific colour coding in their patient appointment schedule. The type of care provided was based on the physician's group allocation (UC-SC or UC-UC).

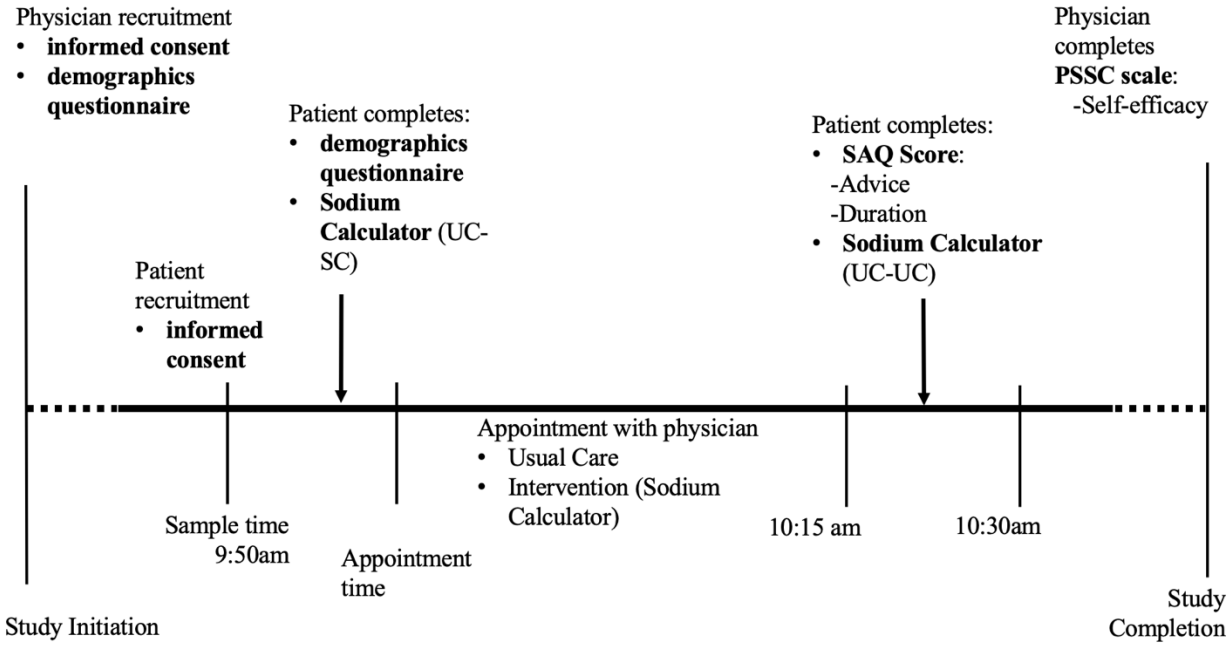
SC Intervention (UC-SC). Physicians in the Experimental Group were instructed to provide usual care for their first five patients, and to use the SC intervention for the following 5 patients. *Usual care* for this study, followed in both groups, was defined as the current practices of each physician for sodium reduction with their hypertensive patients. Physicians were told to follow their usual schedules and procedures, with the exception that there needed to be a mention of dietary sodium reduction in the appointment. The *SC Intervention* included brief overview of the logistics of using the SC with Experimental Group physicians. This included the rationale for the SC, where to find the results of the SC, and a review of outputs/results. These physicians were also provided with low sodium resources to support the SC (which will be included electronically in a new 2019 version of the SC). Physicians were instructed to review the SC results during the appointment with the patient and then discuss dietary sodium. This design will allow for the comparison of within-physician changes in provision of dietary advice between their usual care and after the introduction to the SC intervention in a full-scale RCT.

Control [Usual Care (UC-UC)]. Physicians in the Control Group were instructed to provide their usual care, as described above, to all ten of their study patients.

Patient study protocol. Patient study procedures were completed in a private area of the clinic. Each patient received a unique study ID for completing study materials. After consent was obtained, all patients were asked to complete a demographic survey. Anthropometric data [height (cm) and weight (kg)] and blood pressure were taken by clinic nurses. Patients who were seeing a physician providing usual care went on to their appointment and completed the SAQ Score immediately after their appointment, followed by completion of the SC. Completion of the SC after their appointment was to allow the research team to gain an estimate of sodium intake but to minimize contamination of the appointment (i.e. patient bringing up their SC results with their physician). Patients that were to be provided care from their physician with the SC intervention protocol were asked to complete the SC prior to their appointment so that results could be uploaded to their Electronic Medical Record (EMR). These patients also completed the SAQ Score immediately after their appointment to minimize recall bias.

Once all ten of each physician's patients had participated in the study, physicians were asked to complete a demographic information survey, as well as complete the PSSC Scale (Appendix 6). The PSSC Scale was administered only after completing other study requirements to minimize physician burden, and to prevent possible realization of the true study objectives in order to prevent changes to usual care. Physicians in the Experimental Group (UC-SC) were additionally asked to complete an acceptability questionnaire on the SC intervention (Appendix 8).

Figure 7. Overview of all Pilot Study Procedures



Meetings between the research team and research champion occurred periodically to provide updates or discuss any issues with study implementation. Modifications to the study protocol were made throughout the study timeline to address issues identified with implementation of the protocol.

6.1.4 Feasibility methodology.

Thabane's (2010) four reasons to assess feasibility in pilot studies (feasibility objectives) were used to guide development of feasibility outcomes assessed: 1) process (to assess the feasibility of the steps needed to take place in the main study), 2) resources (the assessment of time and budget issues that can occur during the main study), 3) management (potential human and data optimization issues), and 4) scientific (assessment

of treatment safety, determination of dose levels and response and estimation of treatment effect and its variance). Feasibility outcomes within each of these objectives were collected throughout the study timeline based on direct observations by study personnel, discussions with patients, physicians and clinic staff.

6.1.5 Study outcomes and measures.

Primary outcomes and measures. The primary outcomes were related to the overall feasibility of the study protocol. Specific outcomes measured to determine feasibility were broken down based on Thabane's feasibility objectives as described in Table 9 (Thabane et al., 2010). This was to ensure this pilot study had methodological rigor, which includes using an established framework from which to examine the feasibility of a RCT (Lancaster, Dodd, & Williamson, 2004).

Table 9. Feasibility Objectives, Outcomes and Measures.

Objective	Outcome	Outcome Measure	Description
Process Assesses the feasibility of the processes that are critical to the success of the study.	1. a. Recruitment rate of physicians.	Physician recruitment tracked by research champion and study personnel	The total number of physicians who were approached by the research champion versus the number that participated were recorded throughout recruitment was calculated. This was determined using the number of emails sent by the research champion to physicians in the clinics compared to the number of physicians that signed consent forms between May-October 2018.
	b. Recruitment rate of patients	Patient recruitment rate tracked by clinic and study personnel	Patient recruitment was tracked by clinic personnel on a weekly basis. It was calculated using the number of patients per week in the participating physician's schedules versus number of eligible patients versus the number of eligible patients that signed informed consent.
	2. Characteristics of those likely to enroll	Participant Demographic forms (physicians and patients).	This data was collected using participant demographic questionnaires administered to both physicians and patients. Questions were developed to collect information on both physician and patient factors known to influence physician provision of counselling (i.e. length of practice, patient attitudes etc.). Physicians: 11 question survey with 3 questions on demographic information (age, gender, ethnic background), 5 questions about practice (length of time, specialization, nutrition training, number of patients with HTN seen each week), 2 questions about EMR tools and 1 question about attitudes regarding food and health.
			Patients: 12 question survey with 3 questions on demographic information (age, gender, ethnic background), 2 questions on previous advice received by HCP, 7 questions on current knowledge, attitudes and behaviours of sodium

	3. a. Appropriate inclusion and exclusion criteria of physicians (too limited or too broad)? b. Appropriate inclusion and exclusion criteria of patients	Reflection of discussion with physicians Field notes	The reasons for non-recruitment disclosed by physicians were compared to the eligibility criteria to determine if there were any indications that inappropriate physicians had been approached.
			Discussions were initiated with clinic staff with what the challenges/ considerations were in finding eligible patients. Comments from staff and patients were recorded by clinic staff (field notes). Frequency was not measured for each reason for non-participation.
	4. Complications with physicians or patient recruitment?	Field notes	Reasons for physician non-enrolment or withdrawing from the study were documented based on discussion with non-participating physicians and physicians that dropped from the study.
			Reasons for patient non-enrolment were recorded by the hired clinic staff and study personnel based on discussion with the patient. This was descriptive, the frequency of each issue was not recorded by clinic staff.
	5. How appropriate were recruitment procedures for physicians? For patients?	Reflection of overall recruitment process	This data was collected considering of the recruitment procedures developed (which were based on clinic procedures) versus recruitment strategies in the literature. 'Could any changes be made to improve process?' helped guide this reflection.

Resources Assesses time and resource problems that can occur during the study.	7. a. Retention rate of physicians b. Retention rate of patients	# of signed consent forms	The number of signed consent forms was compared to the number of physicians and patients that contacted study personnel requesting to be dropped from the study.
	8. How did the recruitment procedure impact the clinic staff?	Field notes	Any comments made by clinic staff or complications observed with procedures that impacted flow were recorded. Observations included if the appointments of the study patients consistently ran late, if clinic staff (nurse) assisting with study was consistently unavailable impacting the flow of the doctor's schedule or study schedule, etc.
	9. a. What are the reasons for physicians not enrolling in the study? b. What are the reasons for patient not enrolling in the study?	Field notes	Verbal feedback from physicians that were approached about the study but declined participation was recorded by study personnel, if provided. Reasons noted by patients to not participate were recorded by clinic staff and study personnel. The frequency of each reason was not recorded by clinic staff.
	10. a. Adherence rates of physicians to study protocol b. Adherence rates of patients to study protocol	Note: Adherence was defined as the physician successfully discussing sodium with their patient.	The number of times physicians did not talk about sodium was recorded by the patient-reported SAQ Score (Appendix 4). Frequency of non-adherence was calculated. Frequency of patients that did not complete study tools in their entirety (i.e. demographic questionnaire, as the questions in the SC and SAQ Score are required questions that will not allow submission if not answered)

	11. What are the reasons for non-adherence to the study protocol?	Physician Protocol Prompt Form	For physicians this was collected using the Physician Protocol Prompt Form. Physicians could explain why sodium was not discussed with each patient, once the prompt form was implemented.
		Field notes	Direct observations or discussion with participants was the intended method of data collection, however this was difficult to observe as patients generally completed the tools in confidence.
	12. a. How long did it take for patients to complete the assessments (approximately)? b. How long did it take for physicians to implement the study protocol in patient appointments?	SAQ Score	The minimum and maximum amount of time required for participants to complete study materials was noted. It was not directly timed but was considered successful if the patient did not become late for their appointment. Assessment of length of time physicians spent on study protocol with their patients was measured by Q 11 on the SAQ Score which asked about amount of time spent talking about sodium. It was reported in time increments (<1 minute, 1-4 minutes, 5-9 minutes and >10 minutes). The frequency of each reported time was calculated.
	13. Was the equipment readily available when needed?	Field notes Frequency of issues with technology	Any issues with availability of assessment equipment for clinic staff to take anthropometric measurements and blood pressure when needed (weigh scale, blood pressure cuff etc.) was documented. Any issues with proper functioning of technology was noted.

Management Assesses potential human and data management problems.	20. Did the patients understand how to complete the tasks and questionnaires?	Field notes	Clarification questions asked by patients or physicians to complete the study materials were documented.
	31. Were the patients able to complete the assessment tasks and questionnaires?	Field notes	Any challenges observed or stated by patients completing study requirements was recorded.
	32. Was the partnership with a 'research champion' effective?	Field notes	Review of relationship with research champion. A reflection of what the study personnel were able to do without them, what the research champion was needed for was done to assess this.
	33. Was there appropriate space to conduct patient recruitment/study requirements	Field notes	Any difficulties that were noted with space allotted for implementing patient study protocol (area, availability, privacy) was documented by study personnel.
	34. Were the research assistants able to assist with patient recruitment?	Field notes	A discussion was initiated with research assistants about their experience each time they assisted in clinic (any issues that came up, any questions regarding implementing study protocol etc.).
	35. What other challenges did the research team have?	Field notes, study personnel experience	These were documented throughout the progression of the study timeline as they came up. They were reflective of the study personnel's experiences implementing the study protocol.

Scientific Assesses treatment safety, dose response, effect, and variance of the effect.	36. Were there any outcome measures that should have been assessed that were not?	Field notes	This was assessed both throughout and at the end of study implementation. Documentation of any issues or realizations of limitations or gaps with outcome measures noticed were recorded and reflected on.
	37. Did physicians in the intervention find it to be acceptable?	Physician acceptability survey (Appendix 8)	This questionnaire was administered to physicians in the UC-SC group. It contains 12, 5-point Likert scale (strongly disagree to strongly agree) questions and 12 non-required open-ended questions for the opportunity to elaborate on scale responses. It was developed specifically to assess the feasibility of using the SC as an intervention and is described below.
	38. Did physicians narrate any concerns with study methodology?	Field notes	Study personnel collected data based on direct observation of and discussion with physicians during and upon completion of study regarding any issues or concerns that the physician may have had regarding their experience in the study. Physicians from both Control and Experimental groups were able to provide verbal feedback to study personnel.

Exploratory outcomes and measures. The exploratory outcomes of this study were the examination of the quality of advice on sodium reduction provided by physicians, and self-efficacy in providing this advice. Measurement tools were specifically developed and validated for this protocol prior to its implementation: the SAQ Score and the PSSC scale, and are described in more detail in Chapters 4 and 5.

***Sodium Advice Quality (SAQ) Score*.** The SAQ Score is an 11-question tool developed to rate the quality of physician-patient interactions in regard to discussion and advice surrounding sodium reduction. Most questions require a 'yes', 'no' or 'not sure' response and are weighted to provide a score out of 16 on completion. It aims to collect data on the SC intervention exploratory outcomes of frequency and type of sodium advice provided by physicians, and duration of discussion about sodium (Appendix 4).

The Perceived Self-efficacy for Sodium Counselling (PSSC) Scale. A 12-question survey collecting the extent that physicians feel confident advising on sodium reduction (Appendix 6). Questions were answered on a 6-point Likert scale (Little confidence to Very confident, and not applicable). This was completed by physicians following completion of care for all their study patients. Results of the PSSC Scale in this pilot study are descriptive.

6.1.6 Data analysis.

Primary feasibility outcomes. As mentioned, feasibility outcomes were documented throughout study progression. Upon study completion, data collected was organized according to Thabane's (2010) feasibility objectives. Results were then analyzed in consideration of the criteria to assess feasibility provided by this framework: 1) stop –

main study not feasible; 2) continue but modify approach – feasible with modifications; 3) continue without modifications but monitor closely – feasible with close monitoring; 4) continue without modification – feasible as is. It is suggested to state the criteria considered prior to initiation for a study to be successful, however as this was an exploratory study the feasibility was determined by reviewing the overall process, resources, management, and scientific outcomes described in Table 9 from a pragmatic point of view.

The analysis of pilot studies should be mainly descriptive, however there was some feasibility data collected that was continuous data (recruitment rate, physician adherence rate etc.) which were presented as frequencies and percentages (Lancaster et al., 2004). The ultimate decision of classification of overall feasibility of the study protocol was based on the judgement of the research team.

Exploratory outcomes. Continuous data were presented as means, medians and standard deviations; categorical data were presented as frequencies and percentages. Response data from the PSSC Scale Likert-Scale were collapsed into categories: 'Not at all Confident' and 'Little Confidence' into 'Not Confident', and 'Somewhat Confident' and 'Confident' into 'Confident'. Response data from the SC acceptability questionnaire were collapsed into categories: 'Strongly Agree' and 'Agree' into 'Agree', and 'Strongly Disagree' and 'Disagree' into 'Disagree'. Since these were exploratory outcomes, only descriptive statistics were conducted rather than hypothesis testing. Data was also not analyzed in clusters due to the small sample size. SPSS version 25.0 was used to conduct analyses (IBM Corporation, 2017).

6.3 Results

6.3.1 Feasibility outcomes – Process

Recruitment rate - Physicians. Twenty-one primary physicians were contacted via email by a research champion. Emails contained a brief description of the study, its rationale and a brief description of the protocol. Of those physicians contacted, ten physicians contacted study personnel stating interest in participation, with nine physicians providing informed consent. This was a recruitment rate of 43%.

A lunch information session was trialed at one clinic as a method to recruit physicians. An email was sent out to a list serve of 25 physicians in the clinic informing of the date, time and location of session. A total of seven physicians (28%) who received the email showed up to the information session, however none signed up to participate. This was a recruitment rate of 0%.

Recruitment rate - patients. In the last six months of study recruitment, 1602 patients were screened in participating physician's schedules during the study timeline. Of those patients, 387 had hypertension (24%), but only 151 patients had no conditions affecting memory and met eligibility criteria for appointment type (39%). Of these, 51 patients were interested in participating when the clinic nurse, or later, study personnel called to inform them of the study (34% of eligible). Verbal discussion with the clinic nurses and experience of study personnel indicated reasons for disinterest in participating included: lack of time, especially among patients <65 years of age who were employed, reliance on someone else to transport them to their appointment, overall disinterest in study and/or felt their blood pressure was not of concern. The most commonly reported reason for a lack of recruitment by clinic staff was difficulty contacting patients by telephone; email

was not used as many patients did not have an email address on file. Of those that indicated initial interest in participating, five patients did not participate in the study; two patients failed to arrive with sufficient time to provide informed consent prior to their appointment, one patient had a cancelled appointment, and two patients declined participation during the informed consent process citing that they had more important priorities to discuss with their doctor during their appointment, or discomfort with medical information being collected from their EMR. Therefore, overall the recruitment rate for patients that were eligible was 34%.

Inclusion and exclusion criteria - Physicians. Inclusion criteria was broad for physicians and largely deemed acceptable. Physicians in primary care that provided care to patients with hypertension were targeted and enrolled based on the eligibility criteria. There were no interested physicians that were declined participation. However, one physician was dropped from the study due to frequent non-adherence to study protocols (non-adherence with five patient visits), and a limited number of eligible patients with only six eligible patients agreeing to participate during study enrollment.

Inclusion and exclusion criteria - Patients. Eligibility criteria for participants was initially quite specific and found to be a top barrier resulting in delay of recruitment. The main limiting factor was the reason for the appointment. The eligibility criteria was that patients had to be coming in to clinic for a follow up appointment where blood pressure was likely to be discussed (i.e. blood pressure follow up, anti-hypertensive medication review etc.) or for an annual health exam (physical). One observation was that physicians often did not consistently indicate the reason for an appointment on the schedule, thus the

rationale for appointment was unclear and proper screening for eligibility was not possible. Therefore, clinic nurses recruiting patients were reliant on discussions with physicians to confirm if patients were eligible. To address this issue, the research team broadened the eligibility criteria to include patients who had pre-hypertension or had three or more risk factors for developing hypertension halfway through the study timeline to increase the recruitment rate. These patients were required to have three or more of the following risk factors (Table 10). However, this did not result in a substantive increase in the recruitment rate since this was also difficult to screen for.

Table 10. Risk Factors for Hypertension (3 or more)
Age (>50 years)
Overweight/obesity (BMI >30)
Sleep apnea
Dyslipidemia
Diabetes (Type 2)
Diagnosis of coronary artery disease or left ventricular hypertrophy
History of myocardial infarction or cardiac arrest
Renal insufficiency: eGFR < 50 ml/min/1.73m^2
Current Smoker. Includes Tobacco or Recreational/ E-cigarettes
Alcohol intake exceeding recommendations (>2 drinks/day for men; >1 drink/day for women)

6.3.2 Feasibility outcomes - Resources.

Participant retention - Physicians. One physician in the Experimental Group dropped out of the study prior to completion. This was due to relocation of the physician, not due to factors related to the study. One physician was dropped by study personnel.

Participant retention - Patients. After informed consent, no patient dropped out of study participation.

Impact of research on clinic workflow. Clinic staff were hired as research staff and were responsible for screening for and contacting eligible patients for the study. All were registered practical nurses or registered nurses. These hours were on top of their regular clinic duties. In three of the clinics, these clinic staff were responsible for reviewing physician schedules, calling patients, organizing location of patient recruitment, and collecting patient anthropometric data. This did not cause disruption in the clinic workflow at any of the clinics. However, in one clinic there was a raised concern among some physicians, 10 months into recruitment, regarding clinic staff completing research related tasks during clinic hours, despite no disruptions to workflow. This resulted in the altering of recruitment procedures so that other members of the research team (K. Jefferson) could conduct screening. This was accomplished by giving this study personnel employee status and permission by the physicians to review their patient lists so that the EMR could be accessed. K. Jefferson took over responsibility of study tasks at this clinic and became responsible for the fourth clinic that participated after this. No concerns were raised in the other clinics.

Adherence to study protocols.

Physicians. Overall adherence rate across the entire study timeline was 76% (65/86 patient appointments). The research protocol required physicians in both Control and Experimental groups to discuss sodium with participating patients. However, despite

reminders and colour coding of study patients in the EMR schedule, physicians were not fully adherent to the study protocol. To address this issue part way through the study, the research team developed a 'Physician Protocol Prompt Form' that was printed on bright pink or green paper, depending on if physician was providing usual care or the SC intervention. Patients brought this form to their appointment as a notification that they were participating in the study, to serve as a reminder to the physician. This form also provided an opportunity for physicians to indicate if they discussed sodium, and if not, the reason for not discussing sodium, which allowed the research team to better assess protocol adherence. Once implemented, this form successfully increased the rate of physician non-adherence to study protocol, from fourteen patients in three months prior to the implementation of the form to seven patients in the eleven months after implementation. Overall, in five of those cases there was a discrepancy between physician report on the prompt form and patient response on the SAQ Score, resulting in dropping the patient from the study. In two of those cases the physician indicated that with one patient they did not have the time to discuss sodium, and there were other pressing matters with the other. Recruiting patients more consecutively, accomplished at two clinics, also aided in fewer questions from physicians regarding the study protocol, possibly contributing to the improved adherence.

Patients. All patients whose physician discussed sodium during their appointment completed all study materials. Those patients who did not discuss sodium with their physician were unable to complete the SAQ Score in its entirety due to the nature of the questions. Only four participants missed answering at least one question across all

surveys, and in each case the missing information was in the demographic information form.

Time to Complete Study Protocol.

Physicians. The length of time physicians spent discussing dietary sodium with patients reported to be 1-4 minutes (65% of patient appointments) according to patient report. There was no indication that the study protocol significantly impacted the timing of patient appointments, and upon completion of the study no physicians reported any concerns with the time required to adhere to the study protocol. Time required to complete physician surveys is unknown, as physicians completed these online and independently.

Patients. The amount of time for patients to complete study materials was variable. The length of time to review informed consent and complete all surveys ranged from 15 to 45 minutes, excluding the time spent in the appointment. For patients receiving care in the Experimental Group, the length of time was approximately 20-25 minutes prior to their appointment and 5 minutes after their appointment. For patients receiving usual care, approximately 10 minutes prior to the appointment and 15-20 minutes after their appointment was required.

Availability and reliability of equipment and technology. Blood pressure, height and weight were collected using calibrated equipment belonging to each of the clinics. These measures were taken by the clinic nurse (registered practical nurse or registered nurse) and the equipment was always available. An iPad with cellular data capability was used

for patient data collection as there was not always Wifi available at the clinics. There were occasional issues with lack of service on the iPad, rendering it unable to connect to the online surveys. This occurred a total of seven days in clinic out of 13 months of data collection.

6.3.3 Feasibility outcomes – Management.

Comprehension of the Protocol - Physicians. There were no questions from physicians on how to complete the PSSC Scale or acceptability questionnaire, if applicable, when completed at the end of the study. One physician asked for a reminder on how to complete the SC intervention, however there was a span of three weeks in between intervention instructions and the first participating patient. Another physician in the Experimental Group needed a reminder on how to review the results of the SC. However, there was five weeks in between receiving intervention instructions and the first participating patient due to slow patient recruitment and scheduled clinic staff vacation, delaying patient recruitment. In contrast, physicians in the Experimental Group that received instructions on the intervention protocol less than a week before their first study patient did not have questions or require clarification on the protocol.

Comprehension of the protocol - Patients. Many of the questions from patients were regarding how to complete aspects of the surveys using the iPad or SC. For example, in the SC and in the demographic survey multiple patients asked how to enter age into an open-ended question. There were fewer questions regarding how to answer questions with radio buttons. A common question with completion of the SC was regarding how to answer using the ‘daily’, ‘weekly’ or ‘monthly’ columns. Some patients required clarification on how to answer.

Research space in clinics. All clinics provided study personnel with either an empty exam room or conference room in order to provide a private space for patient recruitment. Providing space for research was not an issue in three of the four clinics. Physicians at the one clinic did not raise concern until 10 months into the study timeline.

6.3.4 Feasibility outcomes – Scientific.

Missing outcome measures. There were a small number of patients that missed responses on the patient demographic form (n=4), therefore missing outcome measures were minimal. However, there was an error in the transfer of data from the SC to the database, resulting in missing SC results, despite efforts from the research team to confirm its proper functioning with developers. Study personnel had also been recording SC results for many of the patients, so this information is available for a portion of the participants.

Acceptability of methodology. Acceptability is the extent that those delivering and receiving the intervention find it appropriate and satisfying (Bowen et al., 2009).
All physicians verbally indicated there were no concerns or comments regarding overall study methodology of either usual care or the SC intervention in both physician groups.

6.3.5 Results of exploratory outcomes.

Physician demographics. There were more male than female physicians that enrolled in the study (71%). Physicians in the Control Group were older (51.3 ± 2.6 versus 42.8 ± 4.8 years old), and had been practicing for longer (20 ± 2.9 versus 14.3 ± 4.0 years). All physicians indicated they had only received a few nutrition lectures during medical

school (Table 11). All physicians also reported they thought health was greatly affected by what we eat, and all except one physician in the Control Group indicated they thought it would be helpful if their EMR included decision support tools about nutrition and diet (86%) (data not shown).

Patient demographics. A total of 65 patients participated. Overall, 50% were male. The overall average age was 69.3 ± 10.1 years, which was similar in both the UC-SC and UC-UC groups, 70.2 ± 9.4 and 68.2 ± 10.8 years, respectively. The majority, 86%, identified as White. The average number of patient comorbidities overall was 3.3 ± 1.6, with an average of 1.0 ± 0.3 types of cardiovascular disease, and patients were taking 1.8 ± 1.1 antihypertensive medications, with an average blood pressure of 137/78 mmHg. High blood pressure was noted in each group (139/77 mmHg and 134/80 mmHg in the UC-SC and UC-UC groups, respectively), which were clinically similar. Estimated dietary sodium intake was high at an average of 2953 mg/day overall (n=40). Patients that were provided care using the SC intervention had estimated mean intake of 2875 mg sodium, with five patients having an estimated intake less than the recommendations (31%). Mean body mass index (BMI) of each group were also clinically similar. A similar number of patients had received previous diet advice from a family doctor and/or registered dietitian in both groups, however, advice provided by physicians was more likely to be about sodium. A larger proportion of patients receiving care from physicians in the Experimental Group stated they were currently trying to follow a low sodium diet (Table 11).

Table 11. Pilot RCT Participant Demographics

	Experimental Group (n=4)	Control Group (n=3)
Physicians (n=7)		
Age (years)	42.8 ± 4.8[1]	51.3 ± 2.6
Male [n (%)]	3 (75)	2 (67)
Length of time in practice (years)	14.3 ± 4.0	20 ± 2.9
Amount of nutrition education: A few lectures during medical school [n (%)]	4 (100%)	3 (100%)
Patients (n=65)	(n=36)	(n=29)
Age (years)	70.2 ± 9.4[2]	68.2 ± 10.8[3]
Male [n (%)]	17 (47)	15 (52)
Number of Comorbidities	3.3 ± 1.6	3.2 ± 1.4
Number of CVD morbidities	1.1 ± 0.3	1.0 ± 0.3
Number of Anti-hypertensive medications	1.6 ± 0.8	2.0 ± 1.3
Blood Pressure (mmHg)		
SBP	139 ± 17.2	134 ± 18.5
DBP	77 ± 12.1	80 ± 13.7
BMI (kg/m^2)	32.3 ± 6.7	31.7 ± 6.3
Received diet advice from a dietitian [n (%)]	11 (31)	11 (38)
Received advice specifically about sodium [n (%)]	2 (18)	4 (36)
Received diet advice from a family doctor [n (%)]	13 (36)	12 (41)
Received advice specifically about sodium [n (%)]	9 (69)	10 (83)
Sodium/salt affects your health [n (%)]		
Agree	33 (92)	23 (79)
Neutral	3 (8)	4 (14)
Disagree	0 (0)	2 (7)
Sodium/sat affects your blood pressure [n (%)]		
Agree	32 (91)[4]	22 (76)
Neutral	3 (9)	4 (14)
Disagree	0 (0)	3 (10)
Participants currently trying to follow a low sodium diet [n (%)]	16 (47)[2]	10 (34)

[1]Data presented as means ± standard deviation (all such values)
[2]n=34
[3]n=25
[4]n=35

Physician self-efficacy. As this is a feasibility study, and to date only seven physicians have completed the PSSC Scale, no true conclusions can be made on the exploratory outcome of if physicians in the Experimental Group have higher self-efficacy than those in the control at this point. However, a descriptive review of the PSSC Scale responses indicate the majority of physicians, 2 (50%) in Experimental and 3 (100%) in Control groups, felt they could work with their patients to select specific strategies to reduce sodium, 2 (50%) in Experimental Group and 3 (100%) in Control Group felt they could help patients overcome barriers to sodium reduction, and 100% in both groups could inform patients about the benefits of dietary sodium on health. There was a range of confidence in personalizing sodium reduction advice for patients in both groups. Interestingly, 2 (50%) of physicians in the Experimental Group indicated they were not confident in assisting a patient with sodium reduction in a brief counselling appointment, whereas 2 (67%) of physicians in the Control Group (no access to SC results) did feel they could assist a patient in reducing sodium in a brief appointment, and no physicians in the Experimental Group felt they could assess their patients' sodium intake. However, only one physician (33%) in the Control Group felt they were able to do this (Table 12).

Table 12. Results of Pilot PSSC Scale

n (%)	**Experimental Group (UC-SC) (n=4)**			**Control Group (UC-UC) (n=3)**		
	Not confident	Neutral	Confident	Not confident	Neutral	Confident
1. I can personalize dietary sodium reduction advice for each patient I see	2 (50)	1 (25)	1 (25)	1 (33)	1 (33)	1 (33)
2. I can collaborate with my patients and formulate a dietary plan for sodium reduction	2 (50)	0 (0)	2 (50)	0 (0)	2 (67)	1 (33)
3. I can determine a patient's readiness to change their behaviour to reduce dietary sodium intake	0 (0)	0 (0)	4 (100)	0 (0)	1 (33)	2 (67)
4. I can assist a patient with dietary sodium reduction during a brief counselling session	2 (50)	1 (25)	1 (25)	0 (0)	1 (33)	2 (67)
5. I can address resistance to change when advising a patient on dietary sodium reduction	1 (25)	1 (25)	2 (50)	0 (0)	2 (67)	1 (33)
6. I can work with my patient to select specific strategies to reduce dietary sodium intake	1 (25)	1 (25)	2 (50)	0 (0)	0 (0)	3 (100)
7. I can help patients identify and strategize to overcome barriers to dietary sodium reduction	1 (25)	1 (25)	2 (50)	0 (0)	0 (0)	3 (100)
8. I can assess a patient's estimated sodium intake	2 (50)	2 (50)	0 (0)	2 (67)	0 (0)	1 (33)
9. I can advise a patient about the health impacts of a low sodium diet	1 (25)	0 (0)	3 (75)	0 (0)	1 (33)	2 (67)
10. I can inform the patient about the benefits of dietary sodium reduction on their health	0 (0)	0 (0)	4 (100)	0 (0)	0 (0)	3 (100)
11. I feel comfortable referring my patient to a dietitian to provide further support	0 (0)	2 (50)	2 (50)	0 (0)	1 (33)	2 (67)
12. I can work with a patient's family/partner to emphasize the importance of dietary sodium reduction	0 (0)	1 (25)	3 (75)	0 (0)	0 (0)	3 (100)

SAQ scores. The mean difference of SAQ scores in the Experimental Group (UC-UC) showed little difference between when the physician provided usual care and when they used the SC with their patient (8.3 ± 3.6 versus 8.0 ± 3.8), however the mean difference of SAQ scores between the first five patients and the last five patients for the physicians in the Control Group was vastly different (8.7 ± 3.0 versus 11.1 ± 2.3). The mean SAQ

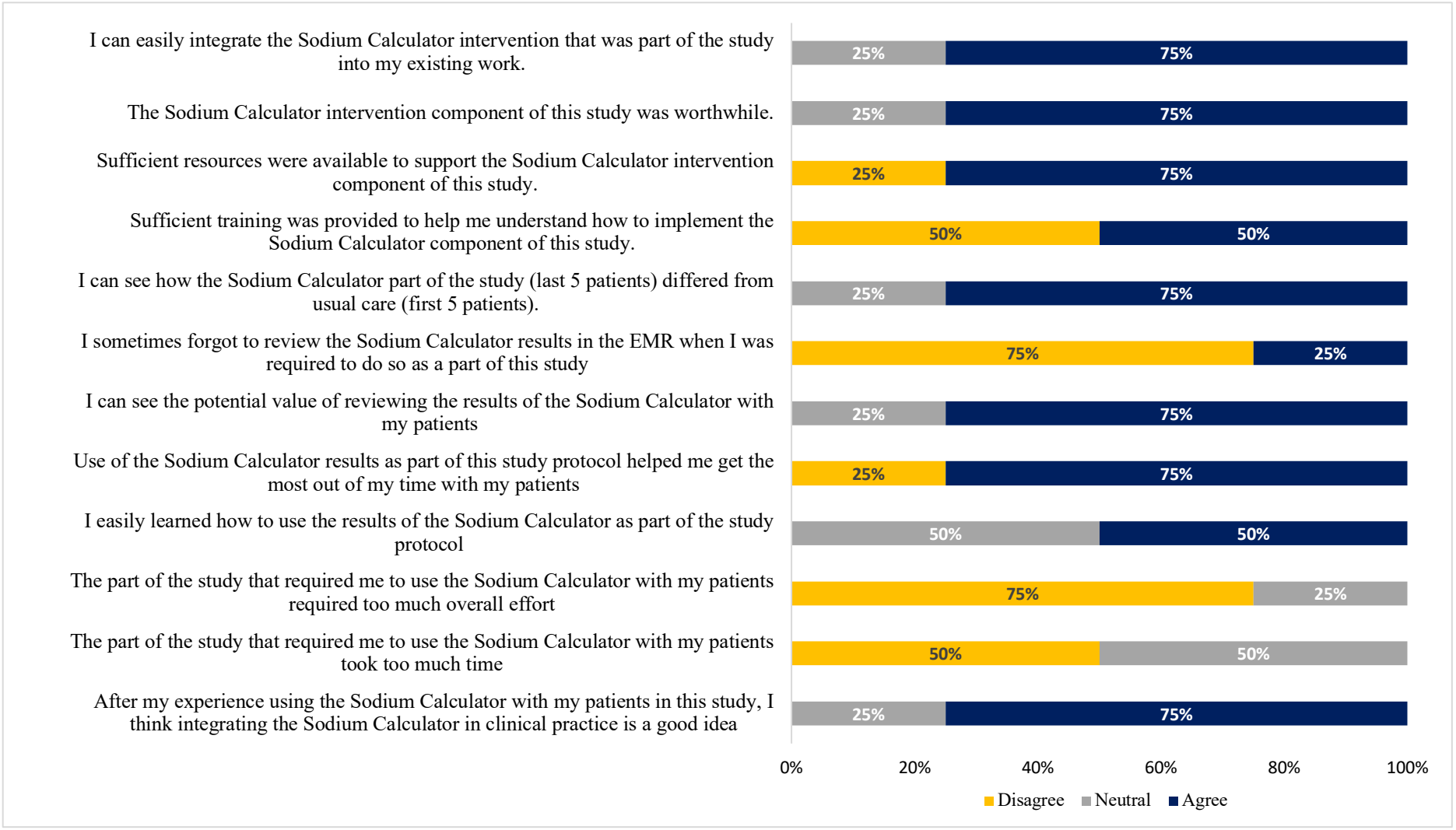
score for both groups (UC-UC and UC-SC) was similar when providing usual care to the first five patients (8.3 ± 3.6 and 8.7 ± 3.0, respectively), however the mean score remained similar for the five patients whose physicians had access to their SC scores (8.0 ± 3.8), while the mean SAQ score increased in the Control Group (11.1 ± 2.3) (Table 13). There were no notable differences in provision of frequency or type of sodium reduction advice within-physician in the Experimental Group (data not shown).

Table 13. Pilot RCT SAQ Scores

n=65	**Experimental Group (UC-SC) n=36**		**Control Group (UC-UC) n=29**	
	UC (n=18)	SC (n=18)	UC (first 5 patients) (n=15)	UC (next 5 patients) (n=14)
SAQ score (mean ± SD)	8.3 ± 3.6	8.0 ± 3.8	8.7 ± 3.0	11.1 ± 2.3
SAQ score median (range)	8 (2-14)	8 (1-15)	9 (3-13)	12 (7-14)

Physician acceptability of the SC intervention. There were four physicians in the Experimental Group (UC-SC) that completed the acceptability questionnaire (Figure 8). Only two physicians provided comments in the open-ended questions. Their feedback included that they thought the SC was useful as it provided a better estimate of sodium intake than what they could discern from a brief conversation with their patient; they did not believe the SC intervention took too much time as all they had to do was review the results, it therefore was not a burden (both physicians); they thought for some patients it was beneficial and they appreciated the 'Physician Protocol Prompt Form' that the patients brought into their appointment as a reminder for the physician to discuss sodium.

Figure 8. Physician Acceptability of SC Intervention



6.3.6. Overall facilitators and barriers to implementation of the protocol.

Finally, overall there were a number of factors and methodologies that supported and impeded successful implementation of the original study protocol. These are important considerations for the development of a large-scale cluster randomized controlled trial and are described below (Table 14).

Table 14. Facilitators and Barriers to the Implementation of the Pilot RCT Protocol

Facilitators	Barriers
Recruitment	
Physician Recruitment	
Engagement of a peer champion (physician) to assist with physician recruitment	
Meeting with physicians 1:1 about study (in person)	Recruitment via group information sessions
	Small compensation for physicians
Patient Recruitment	
Having study personnel responsible for patient recruitment, compared to clinic staff	Difficulty recruiting clinic staff to recruit patients at all of the clinics
	Difficulty relying on clinic staff to recruit patients consistently (different priorities, vacation)
Non-restrictive eligibility criteria	Strict patient eligibility criteria
Protocol Adherence	
Online survey format for physician completed surveys (demographic survey, PSSC Scale)	
Having physicians see study patients more consecutively over a shorter period of time	Large gap of time in between informing physicians in the Experimental Group of the Sodium Calculator intervention protocol and seeing next study patient
Sending study patients into the clinic room with Physician Prompt Form	

6.4 Discussion

This study primarily aimed to determine the feasibility of a RCT protocol designed to examine the impact of the SC on the quality of dietary advice for sodium reduction provided by physicians in primary care settings. The secondary objective was to briefly examine the measurement tools developed to measure the RCT protocol outcomes (exploratory outcomes of advice and self-efficacy). The results identified several areas of success, however, there were also challenges with protocol implementation that need to be addressed. In consideration of Thabane's feasibility criteria, due to the number and magnitude of some modifications throughout the progression of the study, it is suggested that the original protocol was not feasible. However, with the adjustments made throughout the study timeline, it is recommended that if this study is to be implemented as a large scale RCT it is continued with the current, updated methodologies, but some additional modifications are required.

This protocol was successfully implemented in multiple busy primary care clinics (four) with varying staff and administrative procedures, without disrupting the workflow of the physicians. There were no verbally addressed concerns or comments from physicians in the Experimental Group regarding issues with the SC intervention protocol. No indication of the intervention impeding on the overall length of patient appointments was reported by physicians in either group or clinic staff, or observed by study personnel. Therefore, it is implied that the SC implemented as a brief intervention is feasible in this practice setting. However, a number of modifications to the protocol and its implementation were made throughout the timeline to rectify issues that limited, namely, patient recruitment and physician adherence.

The participation rates of both physicians and patients were lower and more challenging than expected, justifying the need for protocol modifications. The literature supports ongoing challenges with participant recruitment in randomized controlled trials (Sully, Julious, & Nicholl, 2013; Treweek et al., 2013). One explanation is this study was implemented in clinics where there was little research experience and exposure. Inadequate research experience and lack of an organizational culture that highly values research is linked to unwillingness of physicians to participate in research studies, suggesting that the location of recruitment of this study may have impacted the recruitment rate (Albers & Sedler, 2004; Rahman et al., 2011; Taylor et al., 1994; Yanagawa, Kishuku, Akaike, Azuma, & Irahara, 2010). Voiced reasons for disinterest in physician participation in this study included establishing a new practice, and a lack of time. Time limitation is a factor continuously reported in the literature as a barrier to recruitment (Asch, Connor, Hamilton, & Fox, 2000). In this study, recruitment was most successful when study personnel were supported by a research champion (physician). However, the future recommendation for physician recruitment in a larger RCT derived from this research protocol is to hire physician recruiters to increase reach. This is a recruitment strategy that is supported in the literature to increase recruitment rates of an unbiased sample, a limitation noted when using a physician-recruiting-physician strategy (Ellis et al., 2007; Treweek et al., 2013).

Difficulty with patient recruitment was also a challenge in this feasibility study. Slow patient recruitment is common in RCTs, with the minority of trials reporting successful recruitment of planned sample size or within the anticipated recruitment timeframe (Sully et al., 2013). Broadening patient eligibility criteria to include patients

with risk factors for hypertension did not result in a substantial increase in patient recruitment as it was difficult to quickly determine patients with these specified, multiple risk factors through a chart screen. The recommendation for patient recruitment strategies in a large scale RCT is to recruit patients randomly using patient rosters belonging to the participating physicians, and to schedule interested patients into specified clinic days for blood pressure related follow up appointments, or hiring a recruitment agency to recruit patients as well. Either of these recruitment strategies would allow for broader patient eligibility criteria by removing type of appointment, a major limitation found in patient eligibility for this study.

Issues with physician adherence to study protocols were also noted in this study. Initial issues with physician adherence were mitigated, resulting in an overall adherence of 76% of patient appointments. Protocols with more extensive physician-based interventions have found difficulties in physician protocol adherence as well (Puczynski et al., 2005), although the literature has tended to focus on patient non-adherence rather than physician. The majority of instances of non-adherence in this study occurred prior to the implementation of the 'Physician Protocol Prompt Form', a reminder for the physician to discuss dietary sodium with that study patient. Therefore, the recommendation for future implementation of this protocol is to continue to use this 'Physician Protocol Prompt Form' to promote physician adherence to the study protocol.

Although no concrete conclusions can be drawn from the exploratory outcomes due to a small sample of physicians and patients, the results of the study tools (SAQ Score, PSSC Scale and the SC acceptability questionnaire) were found to be interesting. Mean SAQ scores of each group did not reflect the expected results of the study. The

mean SAQ scores in the Experimental Group saw no change after the implementation of the SC physician intervention (8.3 ± 3.6 vs. 8.0 ± 3.8), with the mean score staying approximately the same after the use of the SC intervention. However, this may be explained if the patients' SC results reviewed by the physician showed an estimated intake under the recommendations (<2000 mg/d sodium), as the physician may have discussed sodium to follow study protocol, yet not have discussed in as much depth if intake was deemed appropriate. Examination of the SC results for the patients who received care using the SC intervention found that there were 5/16 (31%) patients who had estimated sodium intakes less than 2000 mg/d. These patients gave some of the lowest scores (range of 3-8), which would impact the mean SAQ score in the small sample size. This may instead suggest that the SC can aide physicians in prioritizing discussion about sodium when needed, resulting in efficient care. Additionally, a larger proportion of patients receiving care from physicians in the Experimental Group reported trying to follow a low sodium diet prior to their appointment. This may have contributed to the length and depth of discussion of sodium and sodium reducing strategies with patients receiving care from physicians in the Control Group.

The mean SAQ scores from patients seen in the Control Group were also higher at the end of all ten patients compared to the Experimental Group (8.7 ± 3.0 vs. 11.1 ± 2.3). This is an opposite finding of what was expected considering the hypothesized impact of the SC on provision of counselling; that it would facilitate longer discussion and specific strategies to reduce sodium based on the patient's individualized feedback. It was expected that without use of the SC intervention SAQ scores would remain similar between the first and last five patients for physicians in the Control Group. However, it is

interesting to note that the physicians in the Control Group have been in practice longer than those in the Experimental Group (20 vs 14 years average, respectively), and also rated their self-efficacy as higher for many of the questions in the PSSC Scale. This may have had a significant contribution to the type of advice and length of discussion with their patients, resulting in higher patient reported SAQ scores, since higher self-efficacy has been linked previously to provision of counselling in the literature (Bandura, 1986; Cabana, 1999; Singer, Izhar & Black, 2004; Thompson et al., 1993). It is also possible that patients seen by the physicians in the Control Group have had longer relationships with their physician, and therefore more loyalty to them, since these physicians have been in practice longer than those in the Experimental Group. This also justifies the measurement of self-efficacy in the large scale RCT to account for this possible confounding variable.

In this study, physicians completed the PSSC Scale only once they had provided care to their study patients, it did not account for physician perceived self-efficacy at baseline. This would have provided interesting within-physician changes to assess the impact of the SC on physician self-efficacy with discussing sodium reduction with their patients, an important consideration to help put the results of the PSSC Scale into context with use of the SC. The effectiveness of decision support tools, such as the SC, on physician self-efficacy is not well established in the literature (Bright et al., 2012). Therefore, this would also provide an opportunity to contribute to the knowledge base in this area.

The majority of physicians (75%) supported the benefits of the SC intervention, with only one physician (25%) finding little impact on the care provided and benefit to

using the tool. One important consideration was the physician who reported lower acceptability in using the SC did not find the instructions to use the tool to be adequate, and the resources provided with the tool not sufficient. However, the point of the SC intervention is that it requires minimal training and can be used as a quick assessment tool. It may be an important consideration that instructions for the intervention are provided to physicians either day of or within a week of seeing their next five patients. The next update of the SC will include the addition of patient resources that may possibly support the physician in advising on or discussing sodium, however this has not yet been examined. Additionally, this physician also indicated that at times they forgot to review the SC results, despite a reminder with instructions provided on the protocol prompt form that came into the appointment with the patient.

There were strengths and limitations to this study. Strengths included that data were collected from four clinics to draw feasibility outcomes from, as all clinics had varying staff and procedures that required slight adaptions to the protocol implementation. Although clinics were in the same region, this may increase the generalizability of the feasibility findings to help develop a large scale RCT at other primary care clinics in the future. Another strength was that self-reported measures were developed or adapted specifically for this study protocol and were validated prior to their use. The protocol was designed to minimize recall and reporting bias of these self-reported measures (SAQ Score and PSSC Scale) by having participants complete soon after participation (or directly after their appointment for patients), and preservation of anonymity of data. Limitations of this RCT study protocol were a lack of blinding of study personnel and clinic staff due to the sequential protocol differences between the

Control and Experimental groups. However, this could not and cannot be avoided as the group allocation of the physician impacts the order of study materials to be completed by the patient, which were organized by research staff. Additionally, although physicians were not informed of the detailed study objectives, they were aware that study patients were required to meet with study personnel after their appointment, therefore physicians may have become aware of the true study objectives and changed their care due to the Hawthorne effect.

In conclusion, the original tested study protocol was not deemed to be feasible by the research team, however greater feasibility was demonstrated with the modifications informed and adjusted throughout study implementation, and likely feasible with additional recommended modifications to address issues with recruitment, adherence and resource use. These modifications and recommendations include: 1) recruitment of physicians conducted by physician recruiters to increase reach, 2) recruitment of patients with hypertension from the physician's roster and schedule for blood pressure follow ups on specified clinic days (rather than recruitment of pre-scheduled patients), 3) recruit patients using study personnel or recruiters rather than clinic staff and ensure that all physicians at the participating clinics are agreeable to use of a designated space for research tasks in order to avoid issues with resource use, 4) continue to use a 'Physician Protocol Prompt Form' to help with physician adherence to protocols, and 5) provide explicit directions to patients on how to complete study tools to minimize reporting bias. These are thought to help successfully implement a fully powered RCT to determine effectiveness of the SC intervention on quality of advice on sodium reduction by physicians, and self-efficacy in their ability to provide this advice.

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CHAPTER 7.0: OVERALL DISCUSSION AND CONCLUSIONS

This chapter summarizes important literature as justification for conducting the research in this thesis, a review of the main findings of the three studies in this thesis, and relevant recommendations stemming from the findings.

7.1 Introduction

Hypertension is a leading cause for death worldwide and a risk factor for cardiovascular and cerebrovascular disease related morbidity and mortality (Aburto et al., 2013; Alam et al., 2019; Bromfield & Muntner, 2013; Hornsten et al., 2016). Dietary sodium intakes exceeding 2,000 mg/day is a well-documented causal risk factor for high blood pressure and associated with increased risk for hypertension, cardiovascular diseases and stroke (Aburto et al., 2013; He et al., 2013; Mozaffarian et al., 2014; Nerenberg et al., 2018; World Health Organization, 2012). High sodium intakes have been recently attributed to three million deaths worldwide (World Health Organization, 2013a). Despite these known adverse outcomes, Canadians on average are still consuming too much (Health Canada, 2018). Healthcare providers, including physicians, are key agents of change in promoting health behaviour change in their patients especially among those at highest risk. Since the majority of chronic disease management occurs in primary care settings, with 77% of Canadians visiting their physician annually, this is highly relevant setting for facilitating health behaviour change (Nabalamba & Millar, 2007). However, currently there is poor implementation of nutrition guidelines, such as dietary advice on sodium reduction in primary care settings (Wynn et al., 2010).

Electronic health (eHealth) tools are emerging as a new way of delivering healthcare. These tools show promise in improving adherence to clinical guidelines, access to care, patient-centred care; shared decision making; patient-provider communication, the efficiency of chronic disease management, and overall quality of care improvement (Doocy et al., 2017; George et al., 2009; Hunting et al., 2015; Kreps & Neuhauser, 2010; Marzegalli et al., 2008; Palmier-Claus et al., 2013; Praveen et al., 2014; World Health Organization, 2013a). In Ontario, the healthcare system is currently undergoing transformation, making this is a particularly important time for innovative eHealth interventions which have the potential to provide a means for improving care integration and efficiency. The aims of the newly proposed agency *Ontario Health* are to provide care that is more easily accessible to patients; provide more clinical guidance and effective support for healthcare providers to provide better quality patient care; efficient healthcare spending; and advancement of digital-first approaches to healthcare (Government of Ontario, 2019; Ministry of Health and Long Term Care, 2019). A part of this advancing digital-first approaches to healthcare includes virtual care options for patients to connect with their healthcare providers to receive more accessible and better quality care, which eHealth has the potential to assist with (Ministry of Health and Long Term Care, 2019). Using innovative electronic tools to translate knowledge and improve the effectiveness and efficiency of clinical workflow has been found to be both cost-effective and impactful at improving the health outcomes of Ontarians, including older adults, on the patient level (Sanyal, Stolee, Juzwishin, & Husereau, 2018). eHealth tools, such as the SC, also have the potential to assist healthcare providers more easily and effectively to screen, assess and advise patients about health behaviours, and monitor

progress in adhering to clinical guidelines such as sodium reduction, and has the potential to be delivered through this virtual healthcare delivery. This would an important provision of care for many individuals with hypertension, cardiovascular disease, chronic kidney disease and liver failure who are recommended to reduce their sodium intake, and for their healthcare providers as a part of disease management.

However, at this time there are few eHealth tools routinely implemented into clinical settings to assist healthcare providers in dietary management of their patients, and none to support dietary sodium reduction. The SC (Appendix 7), is an evidence-based eHealth tool developed to assist individuals and healthcare providers rapidly screen and monitor dietary sodium (Arcand et al., 2014). The SC shows potential to improve sodium-related knowledge, attitudes and behaviours, and potentially the intakes of individuals, however it is also plausible that it can support clinicians in the monitoring of their patients' sodium intake (Jefferson K, 2019). Whether or not the SC can support the quality of dietary advice provided by physicians and other healthcare providers, especially those in the busy primary care setting, has not yet been tested.

The objective of this thesis was to determine the feasibility of a RCT protocol that is designed to evaluate the effectiveness of the SC as an eHealth intervention on improving physician-delivered dietary advice on sodium reduction among patients with hypertension in primary care. Since there were no appropriate measurement tools existing in the literature to test this hypothesis, the work in this thesis also included the development and validation of tools to measure the quality of the dietary sodium advice provided by physicians and physician self-efficacy in providing this advice. Overall, this thesis encompasses the first 3 phases of the systematic process of introducing a new

intervention from research into practice considering the *Randomized Trial to Translation Continuum* (Gitlin, 2013): the discovery phase of identifying the clinical problem and current evidence, phase 1 of determining the feasibility and acceptability of the intervention, and phase 2 in conducting an initial test of the intervention through a pilot study. The findings of this work will inform and be integrated into a fully powered randomized controlled trial (RCT) to determine the efficacy of the SC on quality of care provided by physicians to their patients requiring sodium reduction.

7.2 Exploratory Outcome Measures.

The main feasibility study in this thesis (Chapter 6) included a small sample size of both physicians and patients, therefore conclusions or hypotheses cannot be drawn from the exploratory outcome measures (quality of sodium advice, physician self-efficacy) assessed using the Sodium Advice Quality (SAQ) Score and Perceived Self-efficacy of Sodium Counselling (PSSC) Scale. These measures were implemented to mimic the primary outcomes that would be assessed in a full-scale RCT. However, there are some considerations in the implementation of these tools based on the findings from the validation studies conducted in Chapters 4 and 5, and in the preliminary findings in Chapter 6. These findings will guide the successful future implementation of the tools.

Sodium Advice Quality Score. In the validation of the SAQ Score in Chapter 4 of this thesis, it was found that the tool was able to differentiate between healthcare provider delivered high-quality advice and low-quality advice on dietary sodium (14.8 ± 1.3 versus 6.8 ± 3.4, $p < 0.001$), respectively. However, SAQ scores in the low-quality advice group were not statistically similar to the expected score of 5/16 (6.8 ± 3.4,

p=0.065). This may be due to the larger range of scores given by patients in this group and a relatively small sample size. High scores in the low-quality advice group is not surprising as overestimation in the quality of care is cited in the literature with patient exit surveys (Pbert et al., 1999; Sciamanna et al., 2004). These studies have provided caution that patients may overestimate the quantity of the intervention provided when asked immediately after appointments, suggesting that patients may recall previous encounters with their physician. Additionally, in the validation of the tool some patients voiced concern that their physician would "find out" their rating of the quality of the physicians' advice or a that poor score would cause negative consequences for their physician, despite being informed otherwise as part of the study protocol. To minimize possible reporting bias, it is recommended to maintain a protocol that supports the participant in completing the SAQ Score without study personnel learning of their responses, i.e. having the participant complete the tool without the assistance of the study personnel and having the data collected under their unique study ID. It is also vital that when implementing this tool study personnel provide clear, explicit directions to the participant to answer the SAQ Score based solely on the last verbal discussion they had with their healthcare provider in the appointment that day, and ensure the patient is able to complete the SAQ Score confidentially so that the patient is more likely to complete honestly. These clear instructions are also advised to minimize contamination of the SAQ Score responses by what the patient learned from the SC itself.

When interpreting the future results of a full scale RCT that uses the SAQ Score as a measurement of dietary sodium reduction related quality of care it is important to interpret the results with caution. There is evidence to support that physician behaviour

during study patient appointments may be examples of improved clinical practice for those physicians while under observation (Leonard & Masatu., 2010; Leurent, Reyburn, Muro, Mbakilwa, & Schellenberg, 2016). This may explain why the SAQ scores from patients in the Control Group of the feasibility study were found to be higher than expected, and is an important consideration in determining the effectiveness of the SC intervention in the future.

Perceived Self-efficacy of Sodium Counselling. The development and face and content validation of the PSSC scale can be reviewed in Chapter 5 of this thesis. In Chapter 6, physicians completed this tool once they had provided care to their ten unique patients. Physician self-efficacy is an important outcome to measure as it has been found to be linked to the likelihood that they will use brief screening tools and interventions (Nygaard, Paschall, Aasland, & Lund, 2010). However, a limitation of this study protocol was that it did not account for physician perceived self-efficacy at baseline. An interesting observation based on the exploratory outcomes was that physicians in the Control Group (UC-UC) reported more confidence in assisting a patient with dietary sodium in a brief counselling session 2 (67%) of Control Group physicians versus 1 (25%) of physicians in the Experimental Group) on the PSSC Scale. As low physician self-efficacy is linked to poor clinical practice guidelines adherence, including poor rates of counselling about health behaviours for chronic disease management, it would be informative to consider physician's baseline self-efficacy prior to implementation of the RCT protocol to understand the true impact of the SC intervention on physician self-efficacy (Bandura & National Inst of Mental Health, 1986; Cabana et al., 1999;

Thompson et al., 1993). The three physicians in the Control Group also indicated that they had been practicing for longer (20 vs 14 years), which may be associated with increased self-efficacy. Self-efficacy is impacted by quantity and quality of past experiences, and an important consideration in context of the effect of the SC intervention (Zamani-Alavijeh et al., 2019). The effectiveness of decision support tools, such as the SC, on physician self-efficacy is not well established in the literature (Bright et al., 2012). Therefore, this would also provide an opportunity to contribute to the knowledge base in this area.

7.3 Protocol Feasibility Outcome Findings.

Based on the feasibility framework by Thabane (2010), this feasibility study suggests that the SC intervention itself was feasible, however the overall protocol to facilitate physician implementation of dietary sodium reduction advice was not feasible in its initial stages, considering a slow rate of patient recruitment if a full-scale RCT is to be completed in a timely manner. However, with modifications made to the protocol throughout the study timeline and in addition to further recommended changes, it is proposed that a large scale RCT would be feasible. There were a number of factors and methodologies that supported and impeded successful implementation of the original study protocol. These are important considerations for the development of a large-scale cluster randomized controlled trial and can be seen in Table 14 in Chapter 6.

Assessment of study protocol implementation. The feedback received from participating physicians demonstrates that the SC intervention itself was largely

acceptable. Several methodological considerations were made in the development of the study protocol to minimize physician burden of protocol implementation; these proved to be largely beneficial and are thought to have contributed to its success. For example, having recruitment of study patients conducted by another individual other than the physician, and designing physician surveys (PSSC Scale and acceptability questionnaire) in an online format was thought to save time and enable flexibility in study requirement completion for the physicians. However, it is also worth noting that one physician wished to review his own schedule for eligible patients and did so with minimal burden. Seven physicians from four clinics successfully enrolled to participate, with only one physician enrolling and dropping out for a reason unrelated to the study protocol, and one physician being dropped from the study due to poor protocol adherence. The study protocol was implemented into all four clinic locations without interrupting physician workflow, and with a physician protocol adherence rate in 76% of patient appointments. This demonstrates evidence of generalizability of implementation from one clinic to the next. Physician adherence to the study protocol improved once a 'Physician Protocol Prompt Form' reminder was implemented part way into protocol implementation. This suggests that it was likely not the protocol itself that was difficult to adhere to, but rather an issue of remembering which patients were participating. Therefore, it is implied that overall the SC implemented as a brief intervention is feasible in this setting.

However, although some aspects of study implementation were successful, there were some barriers that arose. Subsequently, some modifications were and are deemed necessary. In the initial stages of the study the Ontario Tech University research staff were unable to access the EMR, therefore clinic staff (registered practical nurses and

registered nurses) were initially employed by Ontario Tech University as a strategy to overcome this barrier. Their role was to screen for and recruit eligible patients outside of their employable clinic hours, as well as access the study patient charts to upload the SC results into the EMR. However, at one clinic, well into protocol implementation concerns were raised by two physicians regarding use of clinic resources (clinic staff, exam rooms) for research purposes. This was arguably the largest barrier encountered as it put a temporary halt to patient recruitment, however it was rectified by some modifications: The physician research champion advocated for use of non-exam room clinic space and employed a member of the Ontario Tech University research team (K Jefferson) in order to provide legitimate access to the EMR. Permission was then given by the remaining participating physicians for the research staff to access their patient's information. It is important to note that concerns regarding clinic staff were brought up in one clinic only, 10 months into the study and mainly by a non-participating physician. This also occurred around the time of provincial changes to primary care funding that significant impacted physician compensation, and thus morale. Considering that three out of the four clinics had no concerns with the study protocol or use of resources the study protocol is considered to be largely acceptable, however important lessons were learned from this one clinic that should be considered in future protocol implementation. These include: i) it is in the research team's best interest to have a research champion for each clinic, or team of clinics, that can advocate for the importance of the research being conducted, ii) ensure all physicians at the participating clinics are accepting of the use of a designated research space, or ensure a budget that can allow for the rental of space, and iii) adjust the protocol and recruitment strategies to accelerate patient recruitment to not overburden

physicians or the clinics in terms of resource use. If this study protocol is implemented in a large scale RCT these recommendations should be followed to promote overall study success.

The feasibility outcomes assessed in this study also identified barriers to both physician and patient recruitment and participation. Barriers to recruitment are commonly cited as the greatest barriers among randomized controlled trials (Donovan, Paramasivan, de Salis, & Toerien, 2014; Spaar, Frey, Turk, Karrer, & Puhan, 2009), with noted difficulties in recruiting physicians in a reasonable timeline. For example, most studies examined in a recent systematic review required at least 9 months to recruit physicians from 30-137 clinics, which was more time and effort required than originally expected (Johnston et al., 2010; Sully et al., 2013). Involvement of a physician research champion and scheduling one-on-one recruitment meetings to recruit physicians are documented successful strategies (Asch et al., 2000; Ellis et al., 2007; Johnston et al., 2010; Sellors et al., 2002). Existing literature on physician recruitment strategies is largely outdated, however supports that physician recruitment, and possibly adherence, is impacted by time restraints, concern about the impact of their relationship with their patients, lack of reward and recognition and an insufficiently interesting question (Ross et al., 1999). The largest contributing barrier to physician recruitment in our study was a lack of time, a barrier to research participation in general. A lack of significant remuneration is also a deterrent (Ross et al., 1999; Sully et al., 2013). In the recruitment strategy of a large scale RCT it is important to emphasize the limited physician burden of participation with this protocol, ensure budget applications to funding sources provide fund sufficient remuneration that is comparable to the physician time investment, and to have the

support of a physician research champion who can advocate for participation without coercion.

In a review of randomized controlled trials recruiting patients with chronic diseases, two-thirds of studies did not reach the pre-specified recruitment goal, and almost 50% of trials examined in the United Kingdom required an extension (Sully et al., 2013). In our study, not surprisingly, time was a common barrier to participation from both physicians and patients, similar to other findings (Sully et al., 2013; Treweek et al., 2013). It was also difficult to connect with eligible patient participants, which is another commonly documented challenge (Miller, Bakas, Buelow, & Habermann, 2013).

Common recruitment strategies in RCTs involve recruiting patients from the waiting room, however this would not have allowed for sufficient time to complete informed consent and study materials prior to the patient's appointment in many cases. Social media, pre-mailing or emailing study details to participants are other recruitment strategies utilized in RCTs, however in this study the targeted primary participants were not patients and their eligibility criteria was too specific to successfully utilize social media, which is noted to be cost effective but time consuming (Khatri et al., 2015; Miller et al., 2013). Mailing participants was considered, however thought to be too difficult to coordinate distribution of study information and confirming patient interest when recruiting pre-scheduled patients. Emailing an invitation to participate in the study was also considered, however access to patient emails was not consistently documented in the EMR. Therefore, this study relied on calling patients approximately 3-4 days prior to their appointment. This was found to be the best timing as it was close enough to the appointment that patients were less likely to forget to come early, however it was far

enough away that it gave patients an opportunity to follow up with recruiters if they were not able to get a hold of them initially.

Other barriers to patient recruitment were noted throughout study implementation, in particular the eligibility criteria. Only 9% (151/1602) of screened patients with hypertension who were pre-scheduled to see their physician met the full eligibility criteria (no memory issues, appointment type), which was far fewer than expected. This was surprising since patients with hypertension see their primary care physician more often than patients who do not, with 30% more encounters (Godwin et al., 2015). The eligibility criteria were designed to include patients who would realistically discuss sodium with their physician, thus only appointments for blood pressure related follow ups or bi-annual health visits were considered. However, this unexpectedly and mainly contributed to the low eligibility rate of patients. Subsequently, the research team broadened eligibility criteria to include pre-hypertensive patients or patients with three or more risk factors for developing hypertension, however little impact on recruitment rate was noticed possibly due to difficulty scanning for risk factors in the EMR. Future implementation of this study protocol in large RCT should also consider recruiting patients with hypertension to attend a research-related appointment for a blood pressure monitoring follow-up in order to broaden eligibility and therefore potentially accelerate patient recruitment.

A final barrier to patient recruitment was that many patients reported disinterest in participating, a main reason in other RCTs for lack of participation (Felsen, Shaw, Ferrante, Lacroix, & Crabtree, 2010). Interestingly, but not surprisingly, many reported that ‘their blood pressure was fine’, indicating a possible lack of knowledge of the causal,

linear link between sodium and blood pressure. This may also suggest that patients willing to participate in this study may not be a truly representative sample of the general population. This would need to be taken into consideration when interpreting the findings of the full-scale RCT.

7.4 Recommendations.

Based on the findings of this thesis work, there are a number of recommendations for future research similar to this study, including the next phase of a large-scale randomized controlled trial. Recommendations on education, practice and policy levels are also presented below.

7.4.1 Research recommendations.

1. Employ a recruitment agency to recruit physicians and their patients. This is a recruitment strategy noted in the literature to provide a less biased sample than physician-to-physician recruitment and can increase reach (Ellis et al., 2007; Treweek et al., 2013). However, connecting with a research champion in each clinic, group of clinics, or region will help to support the research environment and is strongly encouraged. These research champions can also provide recommendations regarding the best way for recruitment among that group. When interested physicians are identified, one-on-one meetings tend to be more engaging and successful in recruitment.
2. Attempt to minimize the time commitment required for the study protocol for physicians as much as possible. Although there was success in hiring clinic staff to

identify and contact eligible patients was successful for the majority of this study and in most clinics, there were some barriers that arose including use of clinic resources (i.e. staff) for study tasks. Having a recruitment agency, or at minimum study personnel, conduct patient recruitment is highly favoured to reduce those concerns.

3. In order to minimize the overall length of time commitment of the physician to the study, recruiting eligible patients from the physician's patient roster to come in for physician time solely dedicated to seeing participating patients in a blood pressure follow up clinic is recommended. This is likely to increase physician adherence to study protocols by decreasing the opportunity to forget study protocols, and will broaden the eligibility criteria for study patients. However, if this is not feasible and recruiting pre-scheduled patients is needed, patient contact by phone 3-4 days in advance of their appointment is recommended. This allows for enough time for patients to respond if could not be reached, but not too far in advance that the appointment is forgotten about.
4. Provide clear, explicit directions on how to complete the study tools, especially the SAQ Score, with patients in order to minimize reporting bias.
5. Although not done in this feasibility study due to a small sample size, a pragmatic cluster RCT with stratified randomization of physicians for gender is an important consideration in the design of a large-scale trial for this study protocol. It is documented that female physicians significantly counsel more often on lifestyle behaviours (OR=1.62, P ≤0.001), and feel better prepared (84.2% *vs*. 76.0%, P ≤0.001) and successful in their counselling than male physicians (75.6% *vs*. 68.0%, P ≤0.001) (Diehl et al., 2015). Female providers also spend more time on health

behaviour counselling (Harkin et al., 2018). Therefore, it is important to account for differences in provision of sodium reduction advice between female and male physicians.

6. Based on the proposed link between length of practice, self-efficacy and the use of brief screening tools and interventions, it would also be suggested to stratify for length of practice, if possible, to account for this confounding variable.
7. This work allowed for a sample size calculation to be made for a full-scale RCT. It is estimated that in order to have enough power (90% power) to draw conclusions about the efficacy of the SC as an intervention on quality of care provided by physicians to their patients requiring sodium reduction a sample size of 40 physicians and 20 patients per physician (800 patients total) is needed.

7.4.2 Education recommendations.

1. The literature supports that medical students are not educated and prepared enough to discuss nutrition as a part of disease management with patients. Updating current medical school nutrition curriculum to educate on the importance of and the development of clinical nutrition guidelines in hypertension management, specific recommendations and strategies they can make to help their patients reduce their sodium, and ways that they can monitor sodium intakes in their patients, such as using the SC if it is deemed effective in a phase 3 trial. Training on the use of eHealth tools is recommended as a means of aiding in patient care due to both the evidence to support their benefit for providers and patients, as well as their alignment with the transformations in healthcare that are being proposed in Ontario currently.

7.4.3 Practice and policy recommendations.

1. Upon determination of the efficacy of the SC on its ability to help healthcare providers improve sodium related care provided to patients, the integration of the SC into the EMR is recommended with a prompt for screening and brief assessment. This has been done with other risk factors such as alcohol intake, and cardiovascular disease risk (College of Family Physicians of Canada, 2012; McCormack & Pfiffner, 2017).
2. Integrate the assessment of quality of care provided in hypertension management, especially pertaining to sodium reduction into policy guidelines. This currently is not a part of the indicators for quality elements in *Health Quality Ontario's Quality Matters*, which includes a guide to help improve care for patients and families, and to support healthcare providers (Health Quality Ontario, 2017). As dietary sodium is now considered responsible for the largest number of deaths globally it is vital that the nutrition care provided to patients is frequently assessed for quality (Collaborators, 2019). Measurement tools, such as the SAQ Score, can help quantifiably measure sodium related care provided to patients as a part of adherence to clinical hypertension guidelines.
3. Once efficacy of the SC intervention and implementation of the tool into clinical workflow have been established (Phase 3 and 4 trials according to Gitlin's framework (2013), integration of the SC into the EMR as a clinical tool, as well as the development of appropriate coding/billing for this type of care provided is recommended to encourage physicians to screen and provide brief intervention into systemic workflow.

7.5 Conclusions.

In conclusion, this study showed that the originally developed study protocol would not be feasible to administer as a full-scale RCT, however modifications throughout the study timeline, as well as implementation of further recommended modifications to the methodology would likely result in a successful large-scale RCT study implementation. Exploratory outcomes from the feasibility study and findings from the validation studies for study outcome measurement tools (SAQ Score and PSSC Scale) have provided valuable information related to their validity and implementation as part of an RCT protocol.

It is important to note that barriers found relating to recruitment and adherence are often cited in the literature, suggesting that the barriers experienced in this feasibility study are not uncommon to many other RCT studies and should not be the reason to neglect implementing a phase 3 trial. In consideration of the systematic process of introducing a new intervention from research into practice by Gitlin (2013), it is recommended that a full-scale RCT with the revised study protocol be implemented in the future to determine efficacy and effectiveness of the SC as an intervention on physician provision of advice on dietary sodium reduction.

The results of this thesis have the vital role of assisting in guiding the development and preparation of the next phase of research to determine the effectiveness of the SC intervention. Once this has been assessed in a phase 3 trial, it is important to determine how to normalize the intervention in practice to increase the likelihood of adoption into the intended setting (Gitlin, 2013).

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APPENDICES

Appendix 1: Patient Exit Interview Examples in Literature

Patient Exit Interview (yes or no response) (Pbert et al., 1999)	**Score**
Did your doctor discuss your smoking?	1
Did your doctor advise you to stop smoking?	1
Did your doctor discuss what reasons you might have to want to stop smoking?	1
Did your doctor discuss your past experiences with attempts to stop smoking?	1
Did your doctor discuss difficult situations you might encounter or problems you might have in trying to stop smoking?	1
Did your doctor discuss specific things you could do to deal with these possible problems in stopping smoking?	1
Did your doctor ask you questions about your physical dependency on cigarettes, such as "When do you take your first cigarette of the day?" or "Is it difficult to not smoke when you are in a place where smoking is not allowed?" OR Did your doctor discuss the use of Nicorette gum or nicotine patch with you?	1
Did you agree to stop smoking?	0
Did you agree to cut down on your smoking but not stop?	0
Did you set a specific time/date to stop smoking or begin to cut down?	0
Did you and your doctor put the plan in writing?	1
Did your doctor discuss other related changes you might make, such as beginning an exercise program or learning relaxation exercises or weight loss?	0
Did your doctor give you any written materials about smoking cessation during today's clinic visit?	1
Did your doctor set up or ask you to arrange a future contact time (either phone or clinic visit) to further discuss your smoking?	A "yes" to either Item 14 or 15 counted as one point toward the overall score
Did your doctor state that he/she is planning to discuss your smoking on a future visit?	
Total	/10

Patient Exit Interview (yes or no response) (Sciamanna et al., 2004)	**Score**
Did your doctor discuss your physical activity?	No scoring
Did your doctor advise you to become more physically active?	
Did your doctor discuss what reasons you might have to want to become more physically active?	
Did your doctor discuss your past experiences with physical activity?	
Did your doctor discuss difficult situations you might encounter or problems you might have in trying to become more physically active?	
Did your doctor discuss how FREQUENTLY you should exercise?	
Did your doctor discuss how LONG you should exercise?	
Did your doctor discuss how HARD you should exercise?	
Did your doctor discuss the TYPES of exercise you should do?	
Did you and your doctor put the plan to become more physically active in writing?	
Did your doctor give you any written materials about physical activity or exercise during today's clinic visit?	
Did your doctor state that he/she is planning to discuss your physical activity on a future visit?	

Appendix 2: Expert Feedback Survey – SAQ Score

Sodium Advice Quality (SAQ) Score
Please answer the following feedback questions about the SAQ Score:

General

1. **The questions are direct and specific**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

2. **There are no double-barreled questions (two questions in one)**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

3. **Patients will understand the questions being asked**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

4. **There are no ambiguous questions**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

5. **The questions appropriately measure information regarding dietary sodium advice**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

6. **All of the questions that are relevant to assess dietary advice about sodium reduction and have been included? If not, please provide details of what we missed.**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

7. **There are no questions that are unnecessarily included. If so, please provide details of what should be removed.**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

8. **The language and terms used are understandable by patients**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

9. **The questions are clear and concise**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

10. **The questions are asked in a neutral and unbiased tone**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

11. **The questions asked do not lead the participants to a specific response**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

12. **The questions asked are respectful and mindful towards patients**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

13. **The time it takes to complete the survey is appropriate for primary care clinics**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

14. The format of the survey is appropriate for patients

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

15. In the SAQ Score, have we missed any questions?

---

16. Should any questions be removed?

---

17. Do you feel that this tool will be able to discriminate between high-quality and low-quality sodium reduction advice? If no, please explain why.

Weighting

18. The weighting scheme accurately ranks each question appropriately

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

Comments, Suggestions and/or Revisions

Please provide any additional or specific comments or suggestions you have about the SAQ Score, if desired. If you would like to comment further on a particular questions, please provide the question number in the space provided below.

Appendix 3. Expert Comments and Resulting Modifications on SAQ Score

Round 1

Type of Change	Comments	Modifications
Language	*'By using the term "doctor" everywhere, the tool does not make allowances for different types of caregivers now available in heart failure clinics. Many clinics are run primary by physician assistants, nurse practitioners, nurse specialists and are associated with rehab programs. Patients often do not perceive these interventions as coming from their "doctor". As such, patients may receive excellent counselling, that is not captured by this tool.'*	Terminology was changed: 'doctor' to 'health care professional' throughout the SAQ Score.
Content	'*What about adding a question about a referral to a dietitian to discuss sodium restriction in more detail...or discussion about where the client can go for more information (i.e. community resources/website etc.)...'* *'Perhaps ask if doc provided any handout information to reinforce lower sodium message.'* *'If patients are trained in using the sodium calculator application, I have no further comments. If they are not, it may be worth asking if they were sent home with any reading materials.'* *'Possible additional question: Did your doctor provide you with any resources (pamphlets, websites etc.) about reducing the sodium in your diet?'*	'Did your healthcare provider give you any resources (pamphlets or websites) about lowering the salt/sodium in your diet?' was added as a question to the SAQ Score. (Question 10)
Content	*'Might include a chat re "salt substitutes" re Mrs Dash (K)'*	Sub-question: 'Use spices, herbs, salt free seasonings (like Mrs. Dash) and/or salt substitutes instead of salt during cooking' was added to question 9 in the SAQ Score

Content	***'****Discussion of recommended amount of sodium per day..'* *'I would suggest being more specific in Question 3 ... Is it possible to specify how much sodium (doctors may say how much, but if its not relevant to that patient it is useless - i.e. 1 tsp/day vs. 2000 mg/day etc)'*	The sub-question 'How much salt/sodium did your health care professional recommend you consume in a day?' was added onto question 3. This question was designed as a multiple choice question.
Content	*'Question 6 can be removed... I think this is explained in Question 7...'*	Instead of removing, question 6 was reworded and split into two questions to reflect if HCP talked about foods to eat more and foods to eat less. It was not removed
Content	*'...more specific with Question 7e) about what to look for on a label... i.e. aiming of 5% or less Daily Value of sodium per day'*	Question 7e was updated to be more specific by adding the DV: 'Read the Nutrition Facts Table and select products with less than 5% Daily Value (DV) for sodium or the lowest sodium product available'
Question Construction	*'Question 4 - can you list examples of sources (i.e. packaged foods) as patients may be unaware what 'sources' mean/are referring too....'*	This question was reworded to be easier to understand: 'Did your doctor tell you about what foods are high in salt/sodium in your diet?'.
Question Construction	*'Question 7f) can you add snacks too... "eat few high sodium, ready to eat meals/snacks"'*	'Snacks' was added to question
Question Construction	*'...I think Question 7 f) should be split into two questions'* *'Perhaps question 7f can be separated into 2 questions?*	Question 7f was split into 'Eat fewer high sodium packaged, ready-to-eat meals/snacks' and 'Eat more fresh or frozen fruits and vegetables'
Grammar/Typo	*'Question 7e) I don't think Nutrition Facts Table needs to be abbreviated, as it is not discussed later...;'*	Abbreviation of NFT removed

Expert Comments and Resulting Modifications

Round 2

Type of Change	**Comments**	**Modifications**
Language	*Question 1: 'This wording seems verbose ('did your doctor talk to you about following'). Maybe should be rephrased:* *"…did your doctor recommend a low…"* *"…did your doctor discuss low salt…"* *"…did your doctor mention low…"'*	Question 1: slight wording adjustment: 'did your health care provider talk about salt/sodium'
Question Construction	[Question 4] '*This should be two separate questions:* 1) *Did your doctor recommend that you limit certain foods* 2) *Did you doctor recommend that you eat more of certain foods* *-for analytic purposes, this could show a nice binary to illustrate if doctors are giving more positive ("eat this") or negative ("don't eat that") reinforcements in their approach to dietary change.'*	"Did your health care professional recommend that you limit OR eat more of any specific types of food?" was split into two questions to differentiate between the frequency of providers providing positive or negative advice. Our modification was the separation of this questions into two: "Did your health care professional recommend that you limit certain foods?" and "Did your health care professional recommend that you eat more of certain foods?"

Appendix 4. Sodium Advice Quality (SAQ) Score – Investigator Copy with Scoring

		Scoring
1. In your appointment today, did your health care professional talk about a low salt/sodium diet?	□ Yes □ No □ Not sure	Yes = 2 No = 0 Not Sure = 0
If the answer to question 1 is 'No' or 'Not sure', do not answer the following questions and hand in to the study personnel at this time. If the answer is 'Yes', complete the rest of the questions.		
2. Did your health care professional **start** the conversation about salt/sodium?	□ Yes □ No □ Not sure	Yes = 1 No = 0 Not Sure = 0
3. Did your health care professional talk about **how much** salt/sodium *you* should consume in a day?	□ Yes □ No □ Not sure	Yes = 1 No = 0 Not Sure = 0
If the answer to question 3 is 'Yes', answer the following question below (3a). If the answer is 'No', skip question 3a. and continue on to question 4.		
a. How much salt/sodium did your health care professional recommend you consume in a day?	□ 1500 mg sodium □ 2000 mg sodium □ 2300 mg sodium □ 1 tsp of salt □ Other: _____	1500mg, 2000mg, 2300mg, 1 tsp salt = 1 Incorrect other or No=0
4. Did your health care professional talk to you about what foods are high in salt/sodium?	□ Yes □ No □ Not sure	Yes = 1 No = 0 Not Sure = 0
5. Did your health care professional talk to you about what foods are low in salt/sodium?	□ Yes □ No □ Not sure	Yes = 1 No = 0 Not Sure = 0
6. Did your health care professional explain why it is important to follow a lower salt/sodium diet?	□ Yes □ No □ Not sure	Yes = 1 No = 0 Not Sure = 0
7. Did your health care professional recommend that you limit certain foods?	□ Yes □ No □ Not sure	Yes = 1 No = 0 Not Sure = 0
8. Did your health care professional recommend that you eat more of certain foods?	□ Yes □ No □ Not sure	Yes = 1 No = 0 Not Sure = 0

9. Did you doctor recommend that you (check all that apply):		
a. Avoid adding salt at the table or during cooking	☐ Yes ☐ No ☐ Not sure	No recommendations = 0 1 recommendations = 1 2 recommendations = 2 3+ recommendations = 3
b. Use spices, herbs, salt free seasonings (like Mrs. Dash) and/or salt substitutes instead of salt during cooking	☐ Yes ☐ No ☐ Not sure	
c. Reduce the number of times you eat out at restaurants (either fast food or sit-down) **OR** make most of your meals at home	☐ Yes ☐ No ☐ Not sure	
d. Ask for dressings and sauces on the side when eating at restaurants **OR** reduce the use of condiments	☐ Yes ☐ No ☐ Not sure	
e. Read the Nutrition Facts Table and select products with less than 5% Daily Value (DV) for sodium or the lowest sodium product available	☐ Yes ☐ No ☐ Not sure	
f. Eat fewer high sodium packaged, ready-to-eat meals/snacks	☐ Yes ☐ No ☐ Not sure	
g. Eat more fresh or frozen fruits and vegetables	☐ Yes ☐ No ☐ Not sure	
h. Buy foods labelled as "low sodium" **OR** "reduced sodium" **OR** "sodium free", when option available	☐ Yes ☐ No ☐ Not sure	
i. Drain and rinse canned vegetables and beans/legumes before use	☐ Yes ☐ No ☐ Not sure	
10. Did your health care professional give you any resources (pamphlets or websites) about lowering the salt/sodium in your diet?	☐ Yes ☐ No ☐ Not sure	Yes = 1 No = 0 Not Sure = 0
11. How long do you <u>estimate</u> that you and your health care professional spent discussing how to lower your salt/sodium intake? (select one)	☐ <1 minute ☐ 1-4 minutes ☐ 5-9 minutes ☐ >10 minutes	1 minute = 0 1-4 minutes = 1 5-9 minutes = 1.5 >10 minutes = 2
	Total:	/16

Appendix 5. Expert Feedback Survey – PSSC Scale

Perceived Self-efficacy of Sodium Counselling (PSSC) Scale Validation Questions
Please answer the following feedback questions about the PSSC Scale:

General

1. **The questions are direct and specific**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

2. **There are no double-barreled questions (two questions in one)**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

3. **Physicians will understand the questions being asked**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

4. **There are no ambiguous questions**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

5. **The questions appropriately measure physician self-efficacy providing dietary sodium advice**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

6. **All of the questions that are relevant to assess self-efficacy of providing dietary advice about sodium reduction and have been included? If not, please provide details of what we missed**

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

7. There are no questions that are unnecessarily included. If so, please provide details of what should be removed.

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

8. The language and terms used are understandable by physicians

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

9. The questions are clear and concise

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

10. The questions are asked in a neutral and unbiased tone

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

11. The questions asked do not lead the participants to a specific response

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

12. The questions asked are respectful and mindful towards physicians

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

13. The time it takes to complete the survey is appropriate

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

14. The format of the survey is appropriate for physicians

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

15. In the PSSC Scale, have we missed any questions?

---

16. Should any questions be removed?

---

17. The use of a Likert scale is the most accurate was to capture the depth of information needed to analyze results effectively

Strongly Disagree	Disagree	Neither agree nor disagree	Agree	Strongly Agree

Comments, Suggestions and/or Revisions

_____

Appendix 6. PSSC Scale

1. **I can personalize sodium reduction advice for each patient I see**

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

2. **I can collaborate with my patients and formulate a dietary plan for sodium reduction**

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

3. **I can determine a patient's readiness to change their behaviour**

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

4. **I can assist a patient with sodium reduction during a brief counseling session**

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

5. **I can provide the patient with examples of sodium reduction strategies from which they can choose**

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

6. **I can address a patient's resistance to change when advising on sodium reduction**

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

7. I can work with my patient to identify and select specific sodium reduction goals

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

7. I can help patients identify barriers to sodium reduction

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

8. Considering any tools readily accessible I can assess a patient's estimated sodium intake

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

9. I can advise a patient about the impact of a high sodium diet on their health

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

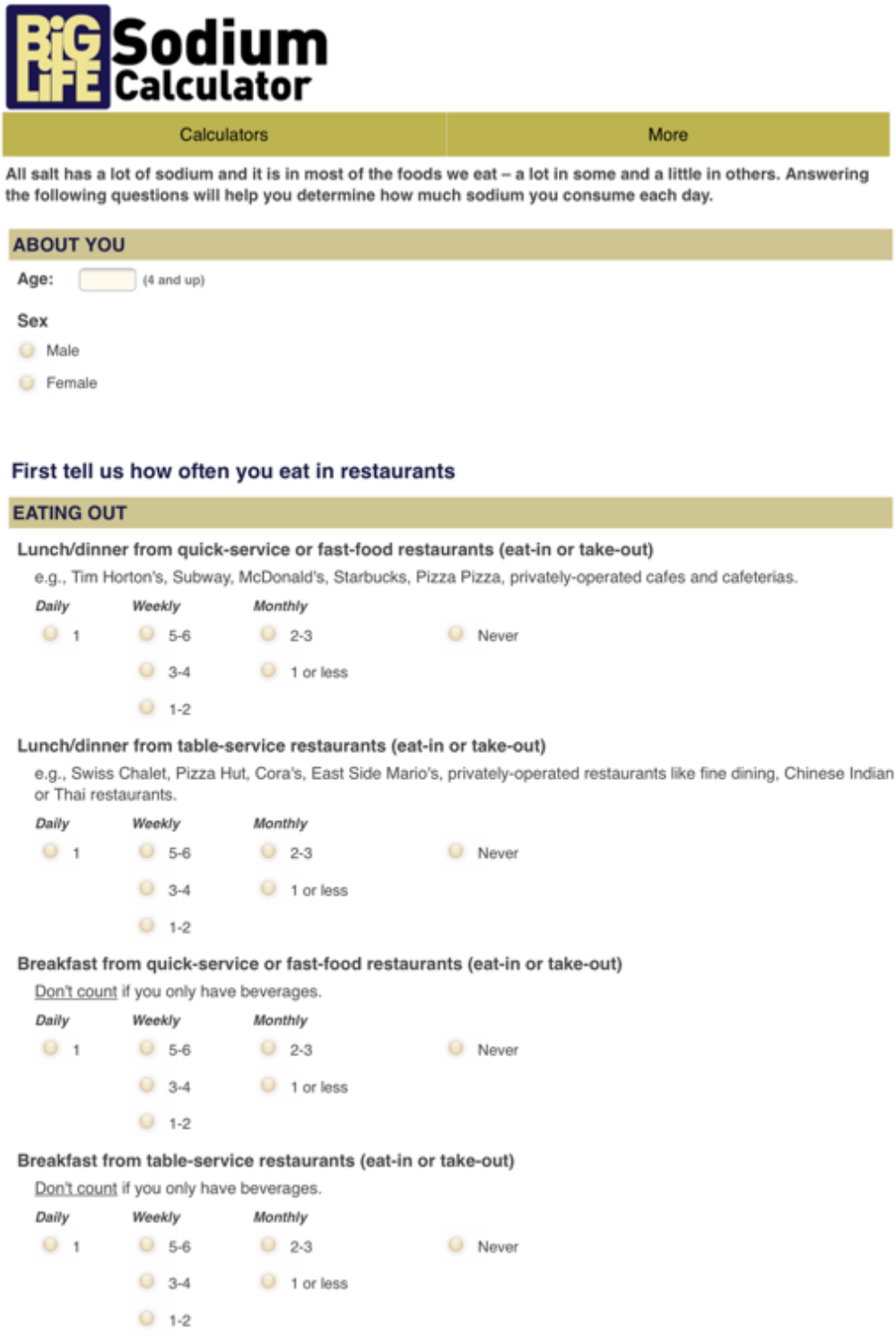
10. I can inform a patient about the benefits of sodium reduction on their health

1	2	3	4	5
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident

11. I feel comfortable referring my patient to a dietitian to provide further support

1	2	3	4	5	
Not at all Confident	Little Confidence	Neutral	Somewhat Confident	Very Confident	Not Applicable

Appendix 7. Sodium Calculator



BIG LIFE Sodium Calculator

Calculators | More

All salt has a lot of sodium and it is in most of the foods we eat – a lot in some and a little in others. Answering the following questions will help you determine how much sodium you consume each day.

ABOUT YOU

Age: (4 and up)

Sex

- Male
- Female

First tell us how often you eat in restaurants

EATING OUT

Lunch/dinner from quick-service or fast-food restaurants (eat-in or take-out)

e.g., Tim Horton's, Subway, McDonald's, Starbucks, Pizza Pizza, privately-operated cafes and cafeterias.

Daily	Weekly	Monthly	
1	5-6	2-3	Never
	3-4	1 or less	
	1-2		

Lunch/dinner from table-service restaurants (eat-in or take-out)

e.g., Swiss Chalet, Pizza Hut, Cora's, East Side Mario's, privately-operated restaurants like fine dining, Chinese Indian or Thai restaurants.

Daily	Weekly	Monthly	
1	5-6	2-3	Never
	3-4	1 or less	
	1-2		

Breakfast from quick-service or fast-food restaurants (eat-in or take-out)

Don't count if you only have beverages.

Daily	Weekly	Monthly	
1	5-6	2-3	Never
	3-4	1 or less	
	1-2		

Breakfast from table-service restaurants (eat-in or take-out)

Don't count if you only have beverages.

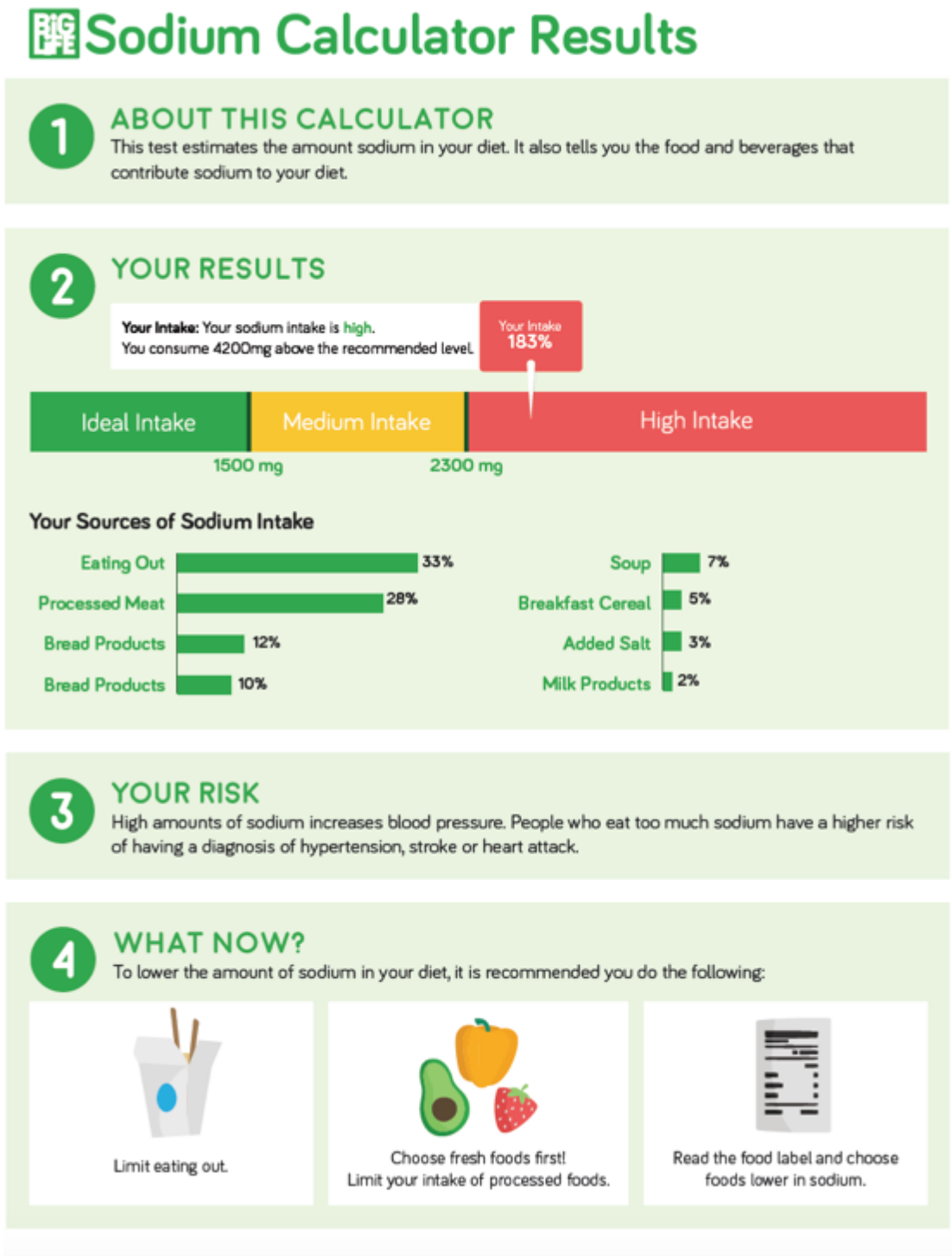
Daily	Weekly	Monthly	
1	5-6	2-3	Never
	3-4	1 or less	
	1-2		

Now tell us how often you eat these foods prepared or eaten at home

BAKERY PRODUCTS & CEREALS

Bread products

B. Sodium Calculator Tailored Feedback (New design)



Appendix 8. SC Intervention Acceptability Questionnaire

1. After my experience using the Sodium Calculator with my patients as part of this study, integrating the Sodium Calculator in clinical practice is a good idea.

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

2. The part of the study that required me to use the Sodium Calculator with my patients took too much time

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

3. The part of the pilot study that required me to use the Sodium Calculator with my patients required too much overall effort

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

4. I easily learned how to use the results of the Sodium Calculator as part of the study protocol

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

5. Use of the Sodium Calculator results as part of this study protocol helped me get the most out of my time with my patients

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

6. I can see the potential value of reviewing the results of the Sodium Calculator with my patients

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

7. I sometimes forgot to review the Sodium Calculator results in the EMR when I was required to do so as a part of this study

Never **Sometimes** **Almost Always** **Always**

8. I can see how the Sodium Calculator part of the study (last 5 patients) differed from usual care (first 5 patients).

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

9. Sufficient training was provided to help me understand how to implement the Sodium Calculator component of this pilot study.

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

10. Sufficient resources were available to support the Sodium Calculator intervention component of this study.

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

11. I agree that the Sodium Calculator intervention component of this study was worthwhile.

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

12. I can easily integrate the Sodium Calculator intervention that was part of the study into my existing work.

Strongly Disagree **Disagree** **Neutral** **Agree** **Strongly Agree**

Appendix 9. Research Ethics Board Approval

Date:	*January 15, 2018*
To:	*JoAnne Arcand*
From:	*Shirley Van Nuland, REB Chair*
File # & Title:	*14625 - Effectiveness of a Web-based Dietary Sodium Screening Tool in Facilitating Physician-Delivered Advice for Dietary Sodium Reduction in Primary Care*
Status:	***APPROVED***
Current Expiry:	***January 01, 2019***

Notwithstanding this approval, you are required to obtain/submit, to UOIT's Research Ethics Board, any relevant approvals/permissions required, prior to commencement of this project.

The University of Ontario, Institute of Technology Research Ethics Board (REB) has reviewed and approved the research proposal cited above. This application has been reviewed to ensure compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 (2014)) and the UOIT Research Ethics Policy and Procedures. You are required to adhere to the protocol as last reviewed and approved by the REB.

Continuing Review Requirements (all forms are accessible from the IRIS research portal):

- **Renewal Request Form**: All approved projects are subject to an annual renewal process. Projects must be renewed or closed by the expiry date indicated above ("Current Expiry"). Projects not renewed 30 days post expiry date will be automatically suspended by the REB; projects not renewed 60 days post expiry date will be automatically closed by the REB. Once your file has been formally closed, a new submission will be required to open a new file.
- **Change Request Form**: Any changes or modifications (e.g. adding a Co-PI or a change in methodology) must be approved by the REB through the completion of a change request form before implemented.
- **Adverse or Unexpected Events Form**: Events must be reported to the REB within 72 hours after the event occurred with an indication of how these events affect (in the view of the Principal Investigator) the safety of the participants and the continuation of the protocol (i.e. un-anticipated or un-mitigated physical, social or psychological harm to a participant).
- **Research Project Completion Form**: This form must be completed when the research study is concluded.

Always quote your REB file number (**14625**) on future correspondence. We wish you success with your study.

Dr. Shirley Van Nuland
REB Chair
shirley.vannuland@uoit.ca

Janice Moseley
Research Ethics Officer
researchethics@uoit.ca